Applicant User Manual
for
Management of Ethics Applications
in
Orion

Version 2 – 21st June 2012

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1. Using this Manual

This manual has been written to support applicants submitting internal Human Ethics Approval for Research Projects at ACU, registration of External Ethics Approval and Application for Taught Unit Approval for current ACU research projects.

Currently, the functions available within Orion are New ACU Project for Ethics approval, but these will expand over time to include all aspects of the Ethics application and management process.

1.1 Ethics Functions

The following table lists the Ethics Processes and where these procedures should take place in the current environment.

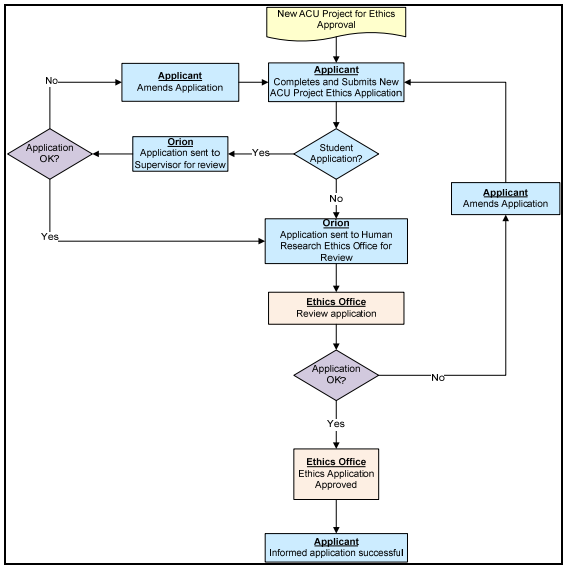
Process	Description	Format
New ACU Project for Ethics approval	Applications and processing of new ethics application for students and academics – Applying – Reviewing – Approval	Orion (from 1st March, 2012)
Registration of External Ethics approval	Registration and processing of projects where the primary HREC is outside of ACU – Registration – Reviewing – Approval	Orion (from 1st March, 2012)
Projects using previously collected non-identified data	Application and processing of projects using non-identifiable data that has been collected previously – Applying – Reviewing – Approval	Orion (from 1st March, 2012)
Application for Taught Unit Clearance	Application and processing of requests for research to be conducted as part of a subject – Applying – Reviewing – Approval	Orion (from 1st March, 2012)
Modification of current/approved ACU project	Processing and documentation of modifications and approvals for these	Word (downloaded from web
Annual Progress Reports	Processing and documentation of Annual Progress Reports required for current ACU projects	Word (downloaded from web)

1.2 Creation and Management of Ethics Applications

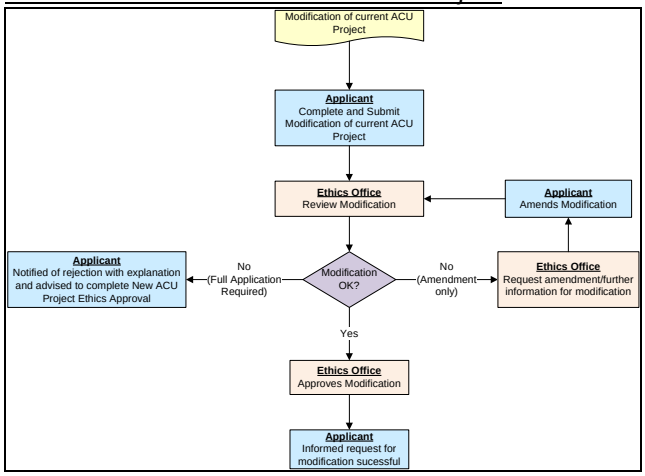
For new Human Research Ethics applications (New, taught units, de-identified data and registration of external ethics approvals), much of the process will be automated through Orion. Once the applicant has submitted their new application, the Ethics Office may request further comments/amendments from the applicant, refer the project proposal to a member of the Ethics

Review Panel or refer the project to the Human Research Ethics Committee. All parties will be kept informed at all stages of this process via email, or by monitoring the progress within Orion itself. All notifications and reminders are automated through Orion.

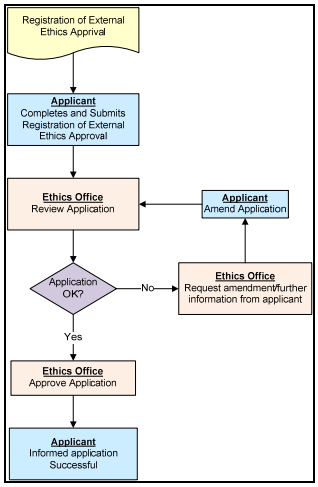
1.2.1 Creating New ACU Project for Ethics



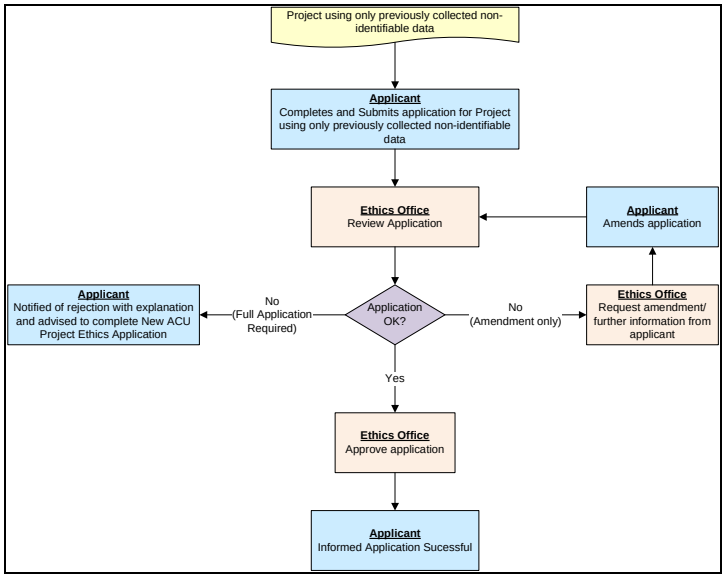
1.2.2 Modification of Current ACU Project



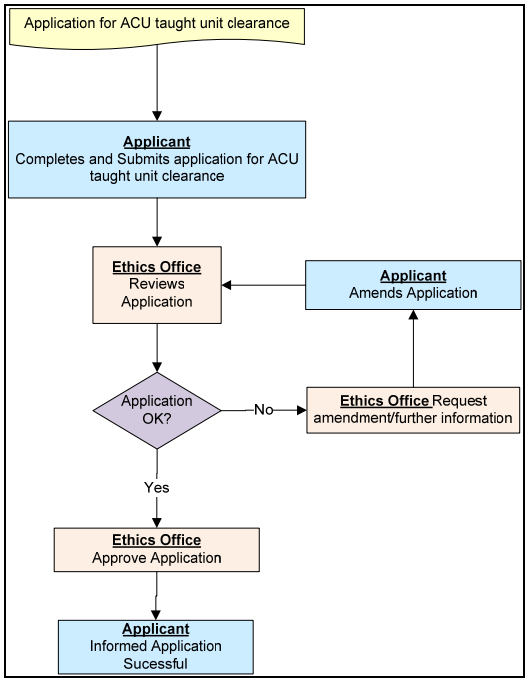
1.2.3 Registration of External Ethics Approval



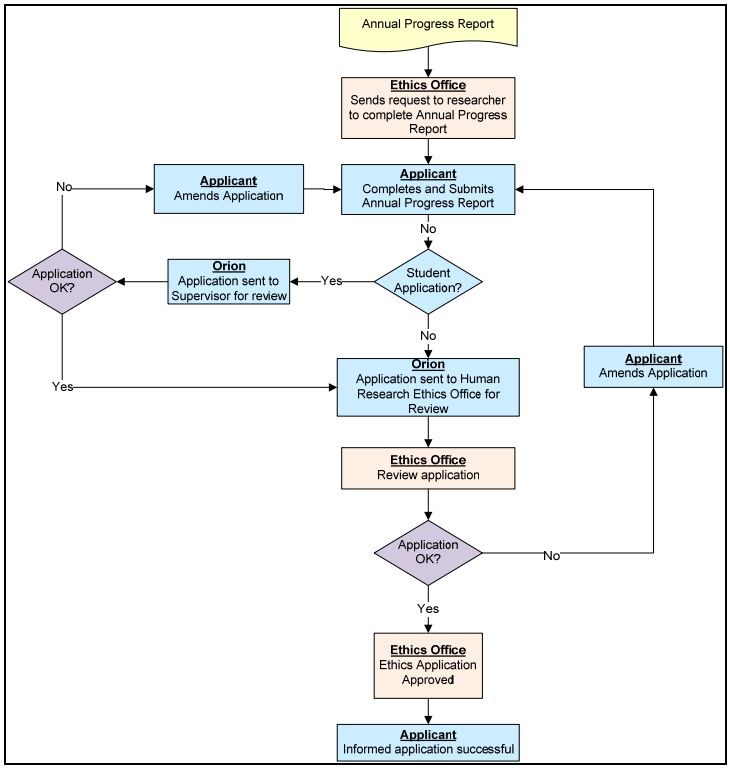
1.2.4 Project using only previously collected non-identifiable data



1.2.5 Application for ACU taught unit clearance



1.2.6 Annual Progress Report

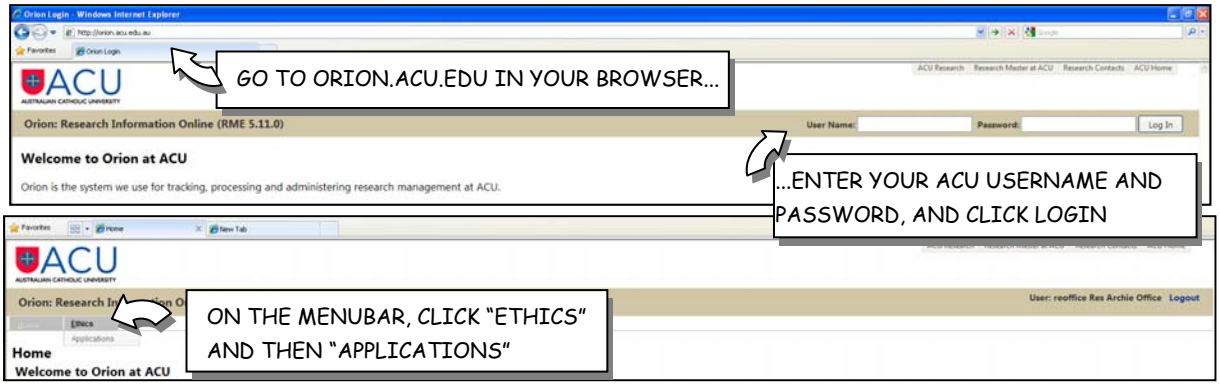


1.3 Queries

If you have any questions regarding this manual, or the Research Ethics Application, please contact Research Services on Extension 3150 or by email to res.ethics@acu.edu.au

2. Access and General Maintenance

2.1 Logging In


GO TO ORION.ACU.EDU IN YOUR BROWSER...
...ENTER YOUR ACU USERNAME AND PASSWORD, AND CLICK LOGIN
ON THE MENUBAR, CLICK "ETHICS" AND THEN "APPLICATIONS"
Orion: Research Information Online (RME 5.11.0)
Welcome to Orion at ACU
Orion is the system we use for tracking, processing and administering research management at ACU.
Home
Welcome to Orion at ACU

2.2 Password Management

2.2.1 Changing your password

Orion passwords are associated with your network login, so will be one and the same. Once you change your network password, the Orion system will automatically pick up the change.

2.2.2 Forgotten Passwords

Forgotten Passwords may be reset using the 'Reset Wizard' when logging into the network.

Otherwise please contact service desk if you are having trouble with password resets:

Email: Servicedesk@acu.edu.au

Phone: (07) 3623 7272

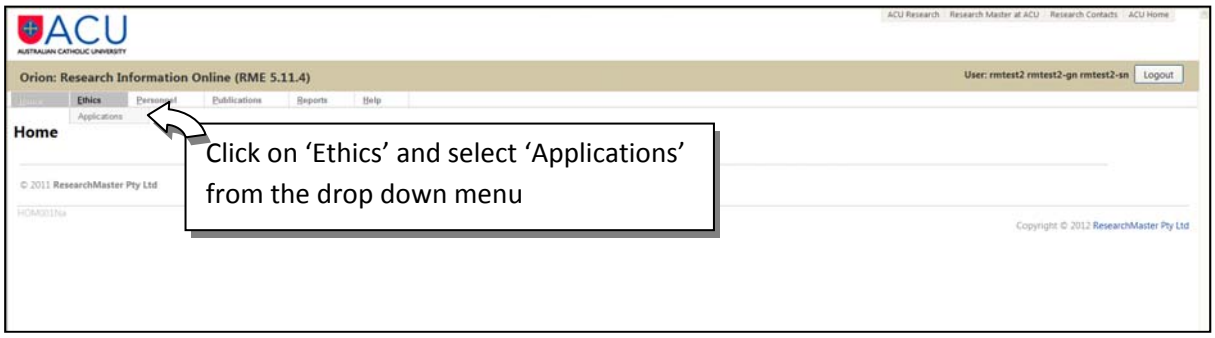
Hours: Monday to Thursday: 7:30am to 7:30pm AEDST.
Friday: 7:30am to 6:30pm AEDST.

3. Work Desk Functions Overview

The Applications Home Page allows selected users to:

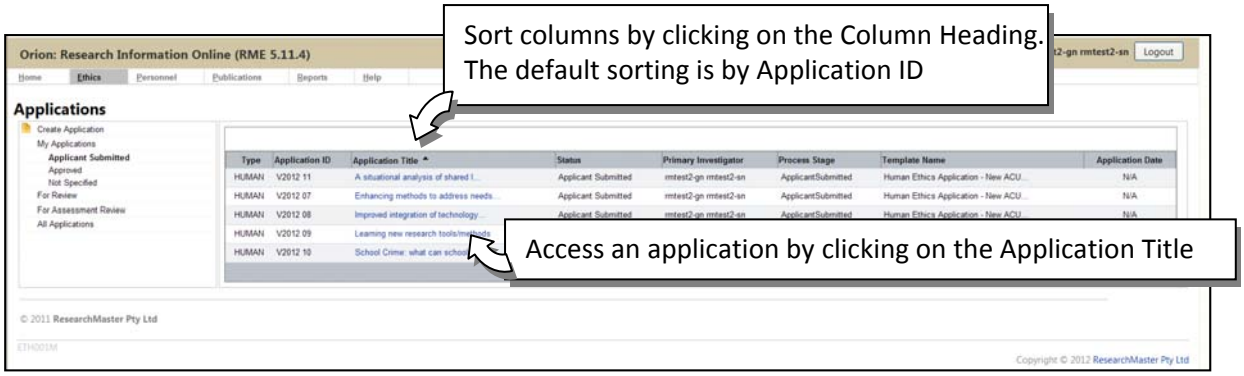
- Create an ethics application using an eForm
- Edit and amend the application
- Submit a completed application for review
- Review an application
- View ethics applications

3.1 Home Page Navigation



The applications home page consists of two areas:

- The function menu on the right which can be accessed to perform functions related to the user's role
- A list of ethics applications you have permission to see


Sort columns by clicking on the Column Heading. The default sorting is by Application ID
Orion: Research Information Online (RME 5.11.4)
Applications
Access an application by clicking on the Application Title

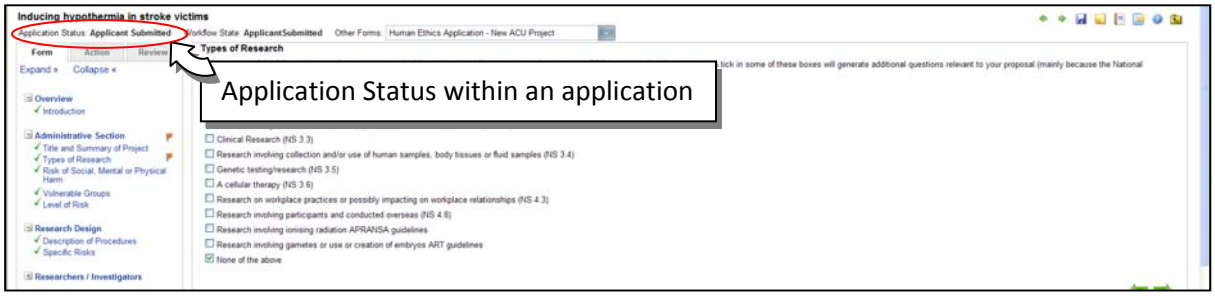
Standard Columns in the Ethics Applications List

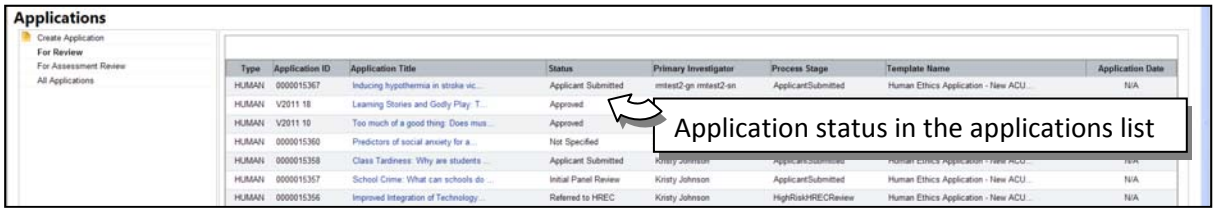
Column	Description
Type	Type of Ethics Application
Application ID	The ID number automatically assigned to the application. Applications are sorted by Application ID in descending order by default. Application ID can be manually changed
Title	Title of the application
Status	Ethics application status

Primary Investigator	The name of the Primary Investigator associated with the Research Project
Process Stage	The name of the workflow process state that the application is currently in
Template	The name of the eForm template used for creation of the application
Application Date	The date the application was made

4. Application Statuses

In Orion, the application status provides the researcher, ethics officer and reviewers with information about where the application sits within the application process. The status is easy to see at any time within the application itself or within the list of applications on the screen.





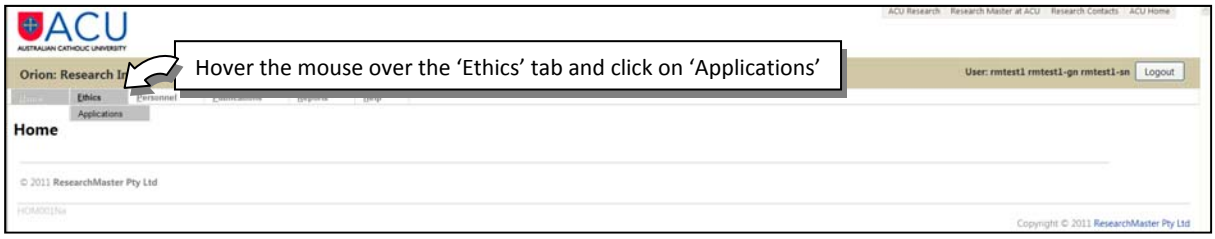
Status/ Significant Date	Workflow Branch	Definition
Applicant Submitted	High & Low Risk	Applicant Submitted Application
Initial Panel Review	High & Low Risk	Student submitted application, Ethics Officer allocates the student's supervisor to review
Revisions	High & Low Risk	Acknowledgement of application, Ethics Officer sends amendment request to applicant prior to Panel/HREC review
Amendment Received	High & Low Risk	Researcher makes requested amendments and submits to Ethics Officer
ERP	Low Risk	Ethics Officer reviews the application and allocates Expediated Review Panel(s) (ERP)
ERP Final Review	Low Risk	ERP member(s) check and submit application back to Ethics Officer
Memo	Low Risk	Ethics Officer sends a memo to researcher after ERP review for amendments
Chair Review	Low Risk	Ethics Officer reviews ERP member approval and sends to ERP chair
Reviewed	Low Risk	EPC reviews the application and approves
Approved	High & Low Risk	Ethics Officer confirms approval of application
HREC	High Risk	Acknowledgement of application- Ethics Officer refers the application to HREC
Chair Review	High Risk	Ethics Officer forwards application to HREC chair- application approved in HREC meeting
Memo	High Risk	HREC reviewed application and amendments required
Rejected	High & Low Risk	Project rejected by HREC/ERP as required changes were not considered/made
Withdrawn	High & Low Risk	Project withdrawn by applicant prior to approval by ERP/HREC

5. Creating a New Ethics Application

New Ethics Applications are created by researchers in Orion and Ethics Officers are notified of these new applications and any changes to applications automatically by emails generated by the Orion module.

5.1 The Applications Home Page

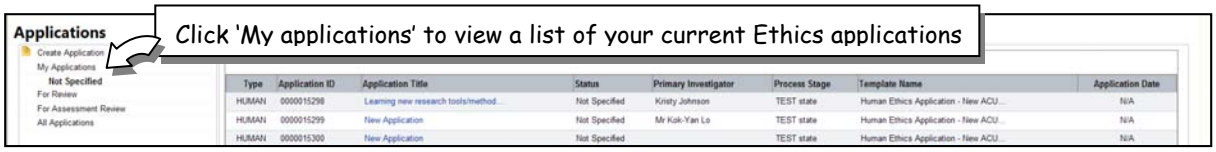
To Access the Applications Home Page:



The Applications Home Page consists of two areas:

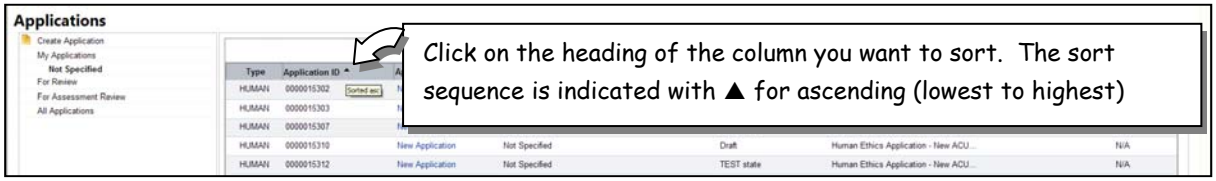
1. The *Applications* menu on the right
2. A list of your Human Research Ethics Applications and the status of the project in relation to the Ethics approval

The application ID, application title, status of application and the date that the application was submitted will be displayed on the page.



All columns can be sorted; the default sort order is by Application ID in descending order so that the most recently created applications appear at the top of the list.

To change the sort order:


Applications
Click on the heading of the column you want to sort. The sort sequence is indicated with ▲ for ascending (lowest to highest)

5.2 Ethics Application Forms and Uses

There are 5 types of forms that are available for use within Orion. In the future all applications, modifications and progress reports will also be completed through Orion. Ethics Application forms include:

- Ethics Scope Checker
  - The Ethics Scope Checker has been designed to assist a potential applicant to check whether or not an activity requires University Ethical Clearance. This tool will pose a sequence of questions to guide the applicant through determining whether or not an Ethics application is should be submitted. At the end of this process, the applicant will either be advised that ethical clearance is required and be directed to which form to complete for the application or informed that ethical clearance is not required.
- New ACU Project for Ethics Approval
  - The New form is used for new Human Research Ethics applications or occasionally when a modification has been submitted, but contains significant changes requiring a new submission
- Modification of Current ACU Project – not in Orion as yet
  - Function currently in RMEWIN
  - The modification of Current ACU Project should be used if an applicant wishes to make changes to their project. For example, changes to:
    - Recruitment Process
    - Methodology
    - Personnel
    - Changes to Participant Information Statement/Consent Form
    - Changes to Advertisements
- Registration of External Ethics Approval
  - Registration of External Ethics Approval should be used where a researcher needs to register an ethics clearance obtained from an HREC at another institution and where the approving institution will remain the responsible HREC.
  - Transfer of Ethics Approval from another university to ACU is also covered by this form
- Project using only previous collected non-identifiable data
  - Research projects using previously collected non-identifiable data are required to complete an abridged version of the full application form. De-identified data is data that cannot be identified with a named individual.
- Application for taught unit clearance
  - An Application for taught unit clearance should be completed when students are required to carry out research as part of taught units in which they are enrolled.
  - In the case of any particular taught unit in which a standard questionnaire is to be completed non-identifiably by the whole student cohort, an application for ethics approval is not required, provided that the data obtained in this manner are simply

aggregated and then used by these same student in exercises designed to develop their report writing skills.

- If students in a taught unit are required to interview one another and/or to interview or administer a questionnaire/survey instrument to people who are not enrolled in that particular unit, ethics approval or exemption from ethics approval must be sought.

- Annual Progress Report – not in Orion as yet
  - Function currently within RMEWIN
  - The Annual Progress Report is used to provide the HREC with a yearly update for research project that required Ethics Approval. It is used by the University to monitor compliance with the conditions, both standard and special, under which research protocols have been approved. This form also serves as the final report required for reporting to NHMRC.

5.3 Accessing Ethics Applications Forms List

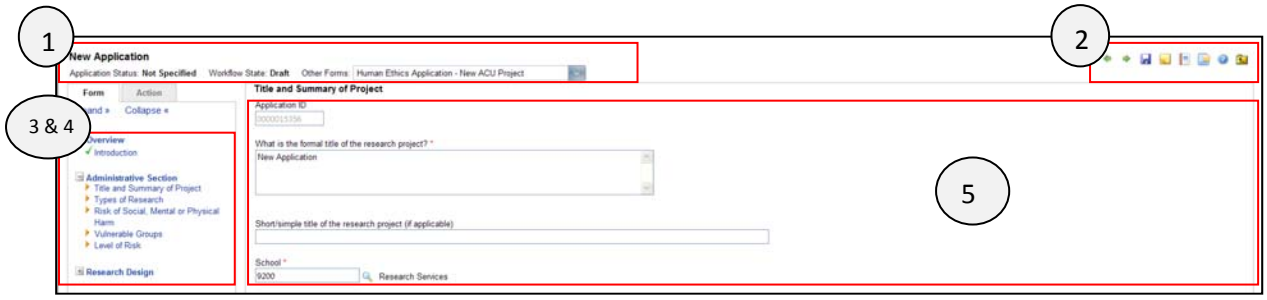
After selecting 'Create Application' a list of applications will appear that are available to you for use. Start with the Scope Checker to determine which form is right for your project.

When you have decided on which form to use for the application, click on the title of the form to start completing your application.

5.3.1 Screen Components within a form

Forms are designed so that applicants sequentially work through each page of the application. Information collected is grouped according to its type, for example all questions relating to privacy are grouped in the one section, general information such as the title, AOU and project start/end dates are in a different section.

Once a page has been completed, the applicant will progress to the next page by clicking the green arrow at the bottom of the page.



1. <u>Information Area</u>

Learning new research tools/methods, Student Access, Internet and Public Libraries
Application Status: Not Specified
Workflow State: TEST state
Other Forms:
Human Ethics Application - New ACU Project

This information area displays the Title and the current status of the application

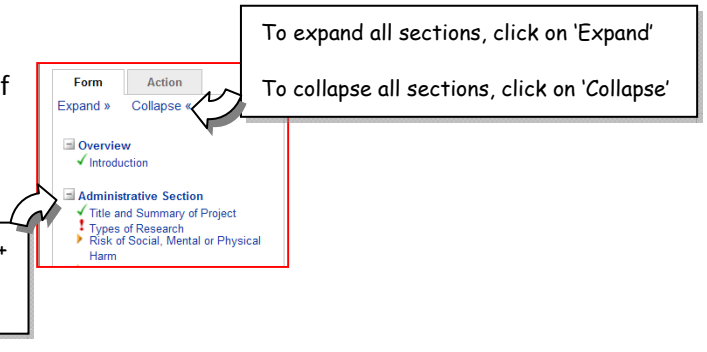
2. <u>Toolbar</u>

The toolbar provides tools for the user to access form related functions

ICON	NAME
	Next Page
	Previous Page
	Save
	Application Comments (comments that relate to the overall application)
	Reports (printing the application, comments or associated documents)
	Page Comments (comments that relate to the current page)
	Help
	Exit the application

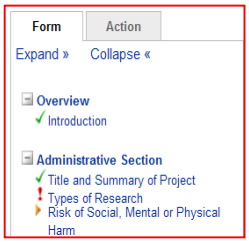
3. <u>Application Form Tree</u>

The left hand panel shows the structure of the form in a tree format and allows access to the workflow actions. It has 2 tabs- 'Form' and 'Action'



4. Application Tree Indicators

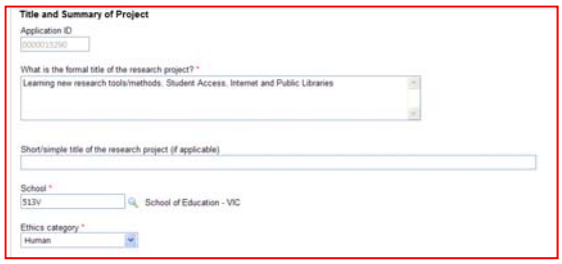
Icons appear on the left hand side of each of the section and indicate which sections are complete, incomplete or have not been accessed.



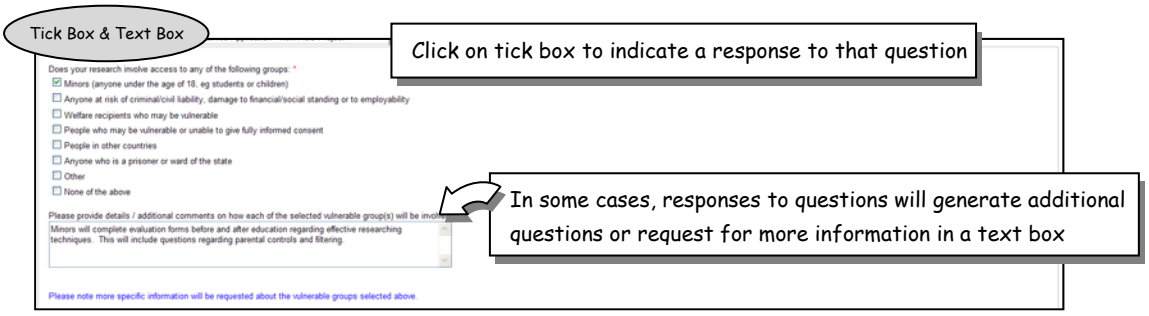
Icon	Description
✓	Indicates that a section is complete
!	Indicates that a section is incomplete – mandatory questions (indicated by *) will need to be completed before an applicant can submit their application
▸	Indicates that a section is yet to be completed

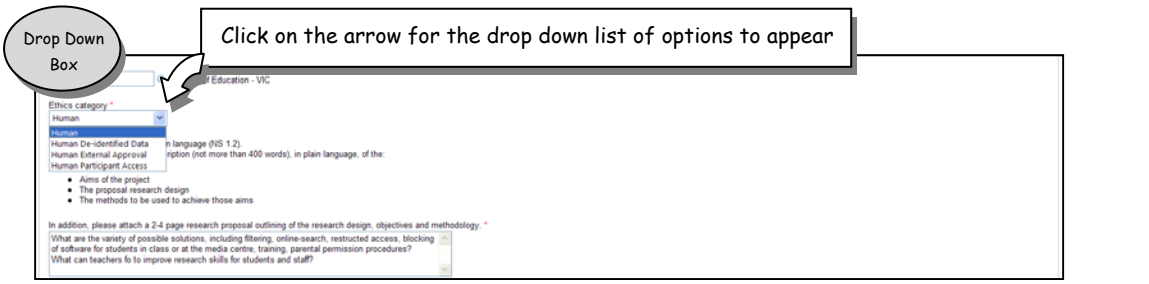
5. Application Form Content

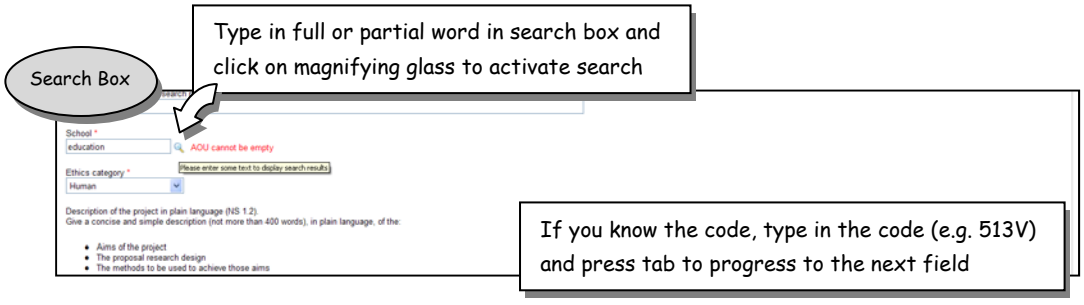
Each page of the application form contains questions regarding the Human Ethics Application. Often additional questions will appear depending on responses to previous questions.

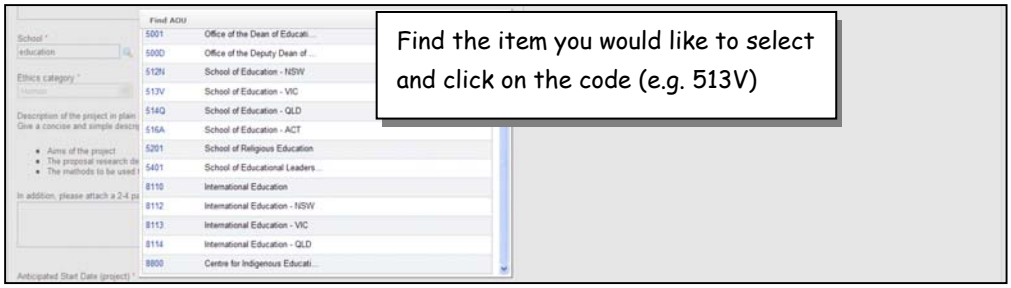

Title and Summary of Project
Application ID
What is the formal title of the research project? *
Learning new research tools/methods. Student Access. Internet and Public Libraries
Short/simple title of the research project (if applicable)
School *
513V
School of Education - VIC
Ethics category *
Human

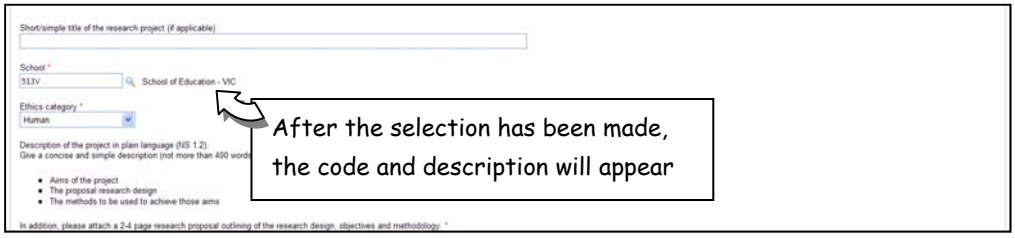
5.4 Field Types

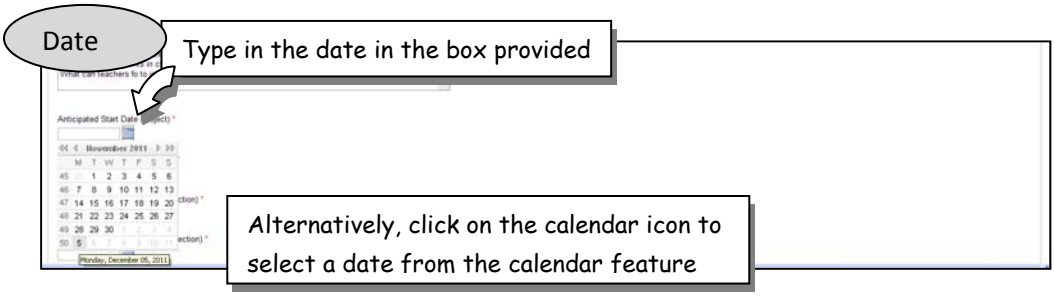

Tick Box & Text Box
Click on tick box to indicate a response to that question
Does your research involve access to any of the following groups: *
Minors (anyone under the age of 18, eg students or children)
Anyone at risk of criminal/civil liability, damage to financial/social standing or to employability
Welfare recipients who may be vulnerable
People who may be vulnerable or unable to give fully informed consent
People in other countries
Anyone who is a prisoner or ward of the state
Other
None of the above
In some cases, responses to questions will generate additional questions or request for more information in a text box
Please provide details / additional comments on how each of the selected vulnerable group(s) will be involv
Minors will complete evaluation forms before and after education regarding effective researching techniques. This will include questions regarding parental controls and filtering.
Please note more specific information will be requested about the vulnerable groups selected above.


Drop Down Box
Click on the arrow for the drop down list of options to appear
Education - VIC
Ethics category *
Human
Human
Human De-identified Data
Human External Approval
Human Participant Access
language (NS 1.2).
ription (not more than 400 words), in plain language, of the:
Aims of the project
The proposal research design
The methods to be used to achieve those aims
In addition, please attach a 2-4 page research proposal outlining of the research design, objectives and methodology. *
What are the variety of possible solutions, including filtering, online-search, restructed access, blocking of software for students in class or at the media centre, training, parental permission procedures?
What can teachers fo to improve research skills for students and staff?

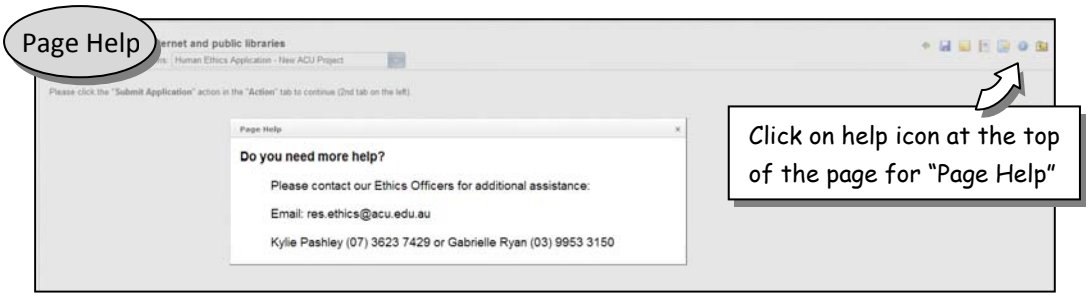

Search Box
Type in full or partial word in search box and click on magnifying glass to activate search
School *
education
AOU cannot be empty
Please enter some text to display search results
Ethics category *
Human
Description of the project in plain language (NS 1.2).
Give a concise and simple description (not more than 400 words), in plain language, of the:
Aims of the project
The proposal research design
The methods to be used to achieve those aims
If you know the code, type in the code (e.g. 513V) and press tab to progress to the next field

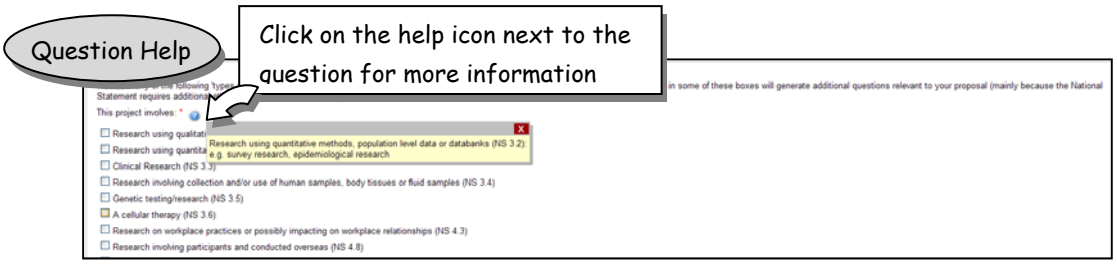





Date
Type in the date in the box provided
Alternatively, click on the calendar icon to select a date from the calendar feature

5.5 Help Files

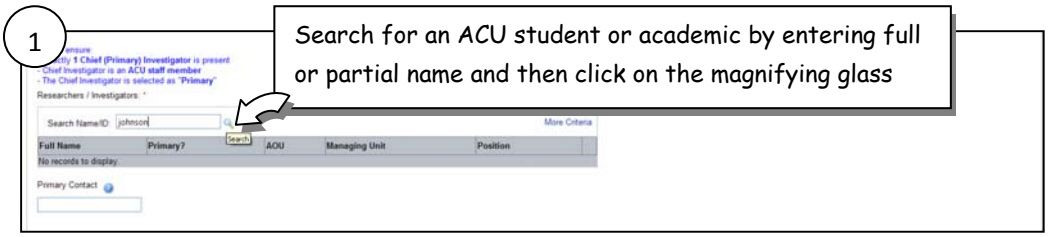

Page Help
Click on help icon at the top of the page for "Page Help"
Do you need more help?
Please contact our Ethics Officers for additional assistance:
Email: res.ethics@acu.edu.au
Kylie Pashley (07) 3623 7429 or Gabrielle Ryan (03) 9953 3150



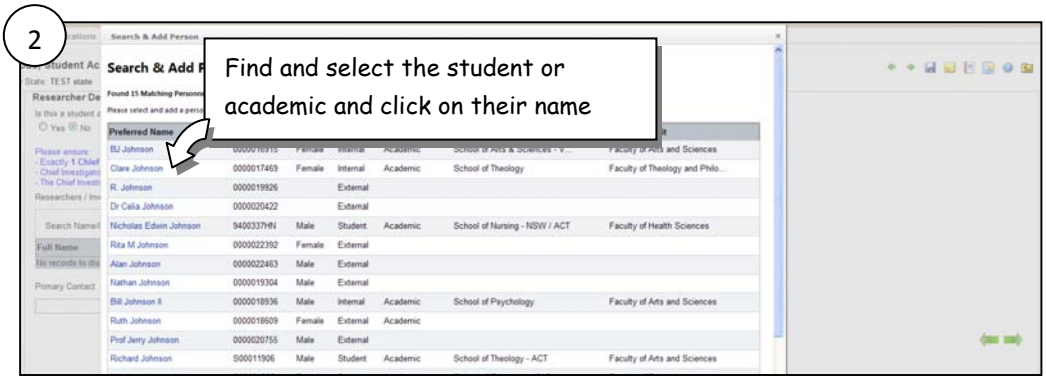
5.6 Assigning a researcher

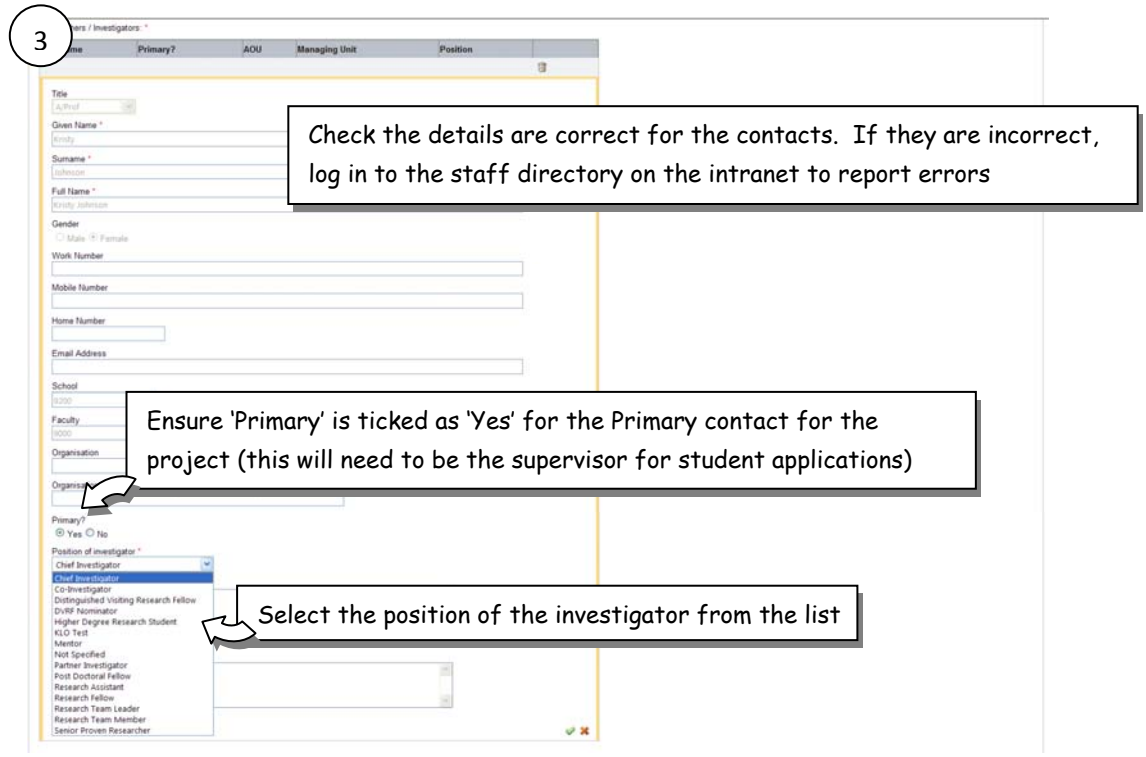
Please note: for student applications, please ensure the student's supervisor is selected as the Chief Investigator and the Primary contact

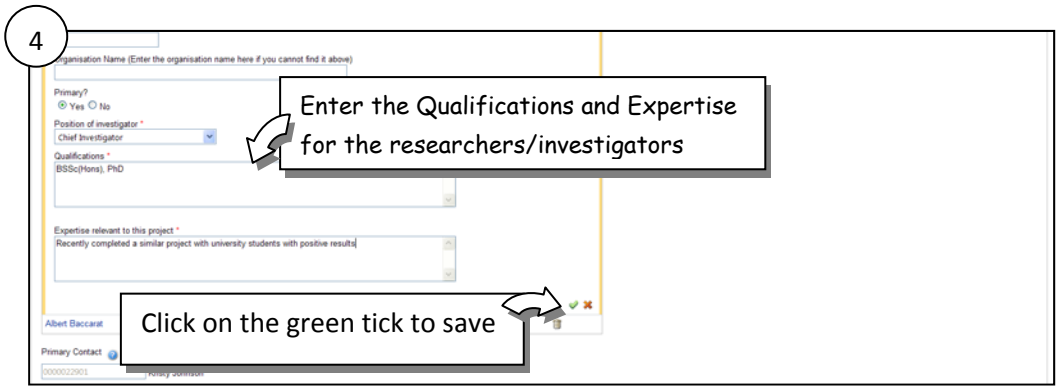
1

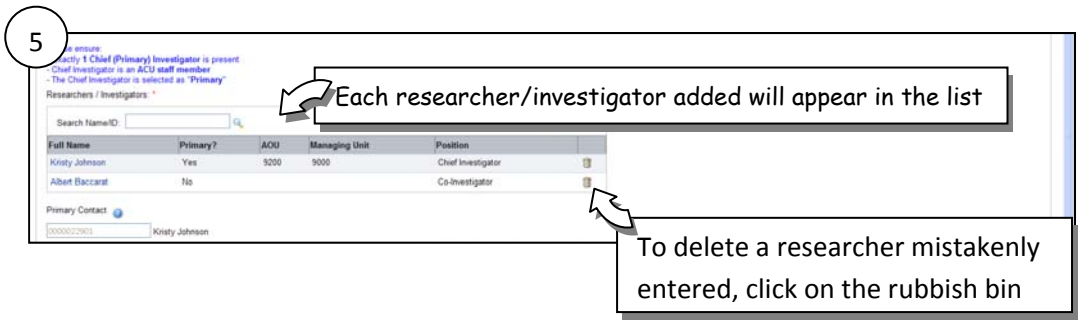


2



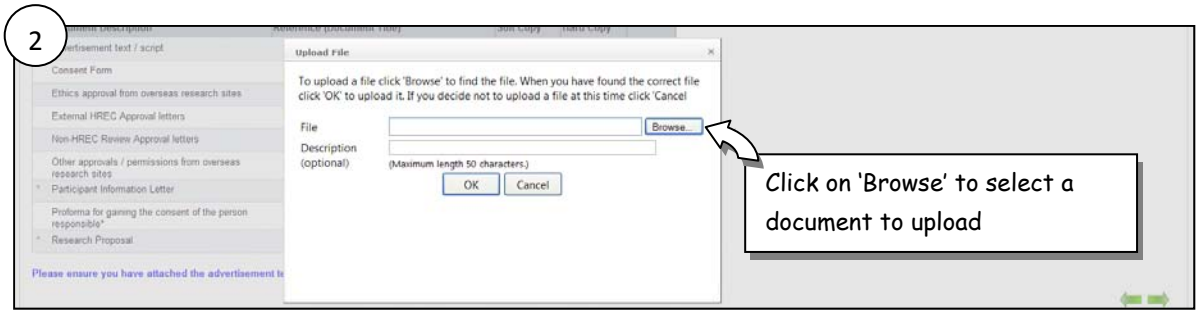

3
Check the details are correct for the contacts. If they are incorrect, log in to the staff directory on the intranet to report errors
Ensure 'Primary' is ticked as 'Yes' for the Primary contact for the project (this will need to be the supervisor for student applications)
Select the position of the investigator from the list



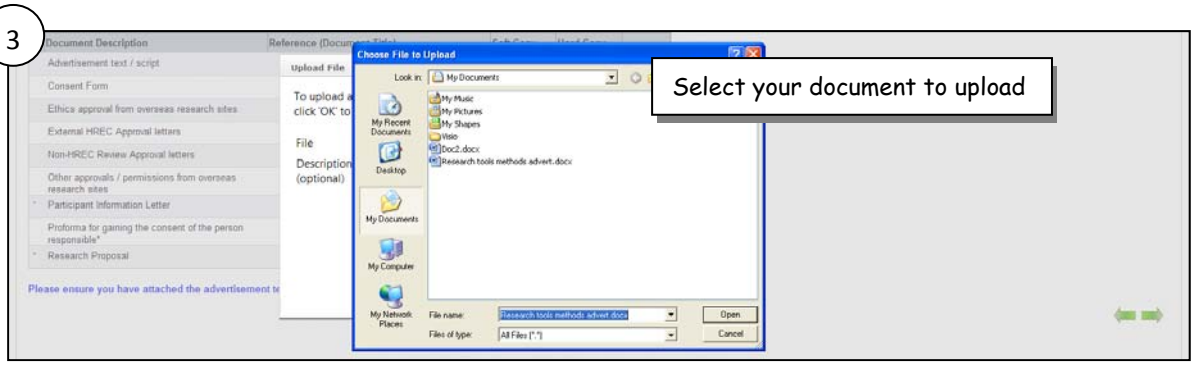

5
Each researcher/investigator added will appear in the list
To delete a researcher mistakenly entered, click on the rubbish bin

5.7 Adding attachments

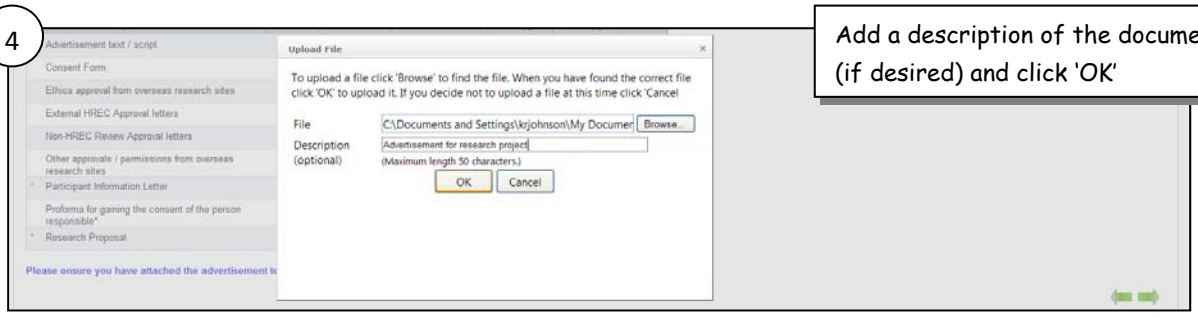
2


Upload File
To upload a file click 'Browse' to find the file. When you have found the correct file click 'OK' to upload it. If you decide not to upload a file at this time click 'Cancel
File
Browse...
Description (optional)
(Maximum length 50 characters.)
OK
Cancel
Click on 'Browse' to select a document to upload

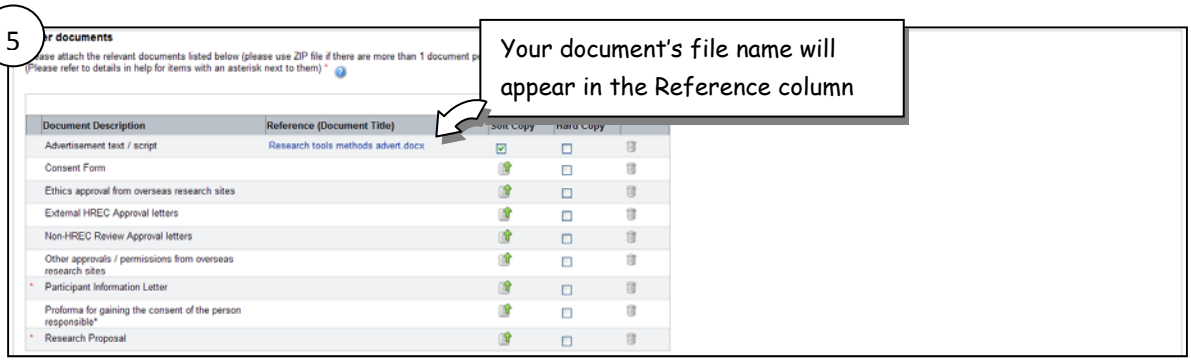
3



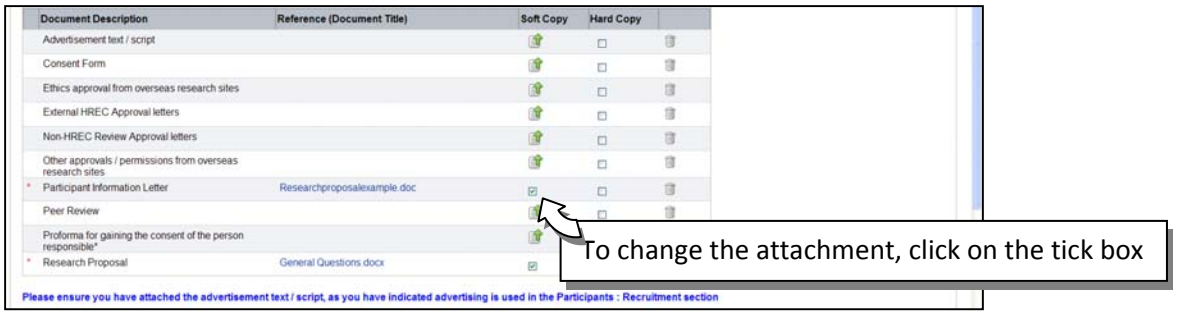
4

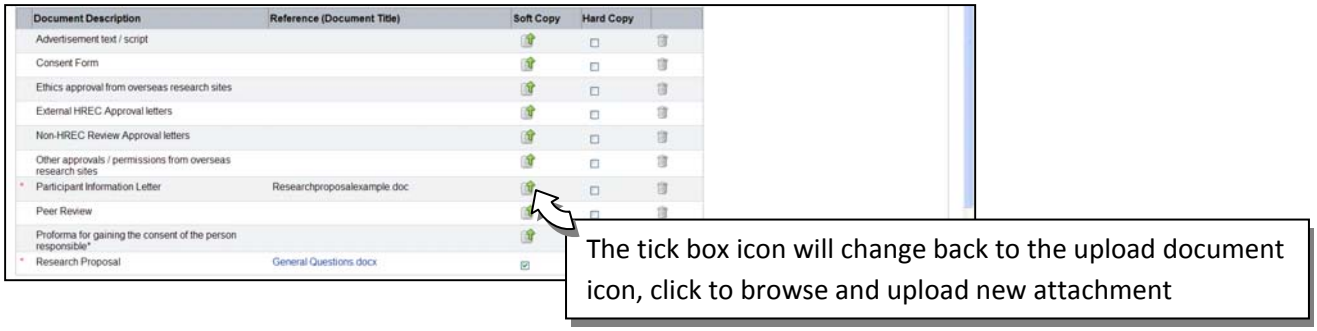

Upload File
To upload a file click 'Browse' to find the file. When you have found the correct file click 'OK' to upload it. If you decide not to upload a file at this time click 'Cancel
File
C:\Documents and Settings\krjohnson\My Documer
Browse...
Description (optional)
Advertisement for research project
(Maximum length 50 characters.)
OK
Cancel
Add a description of the document (if desired) and click 'OK'

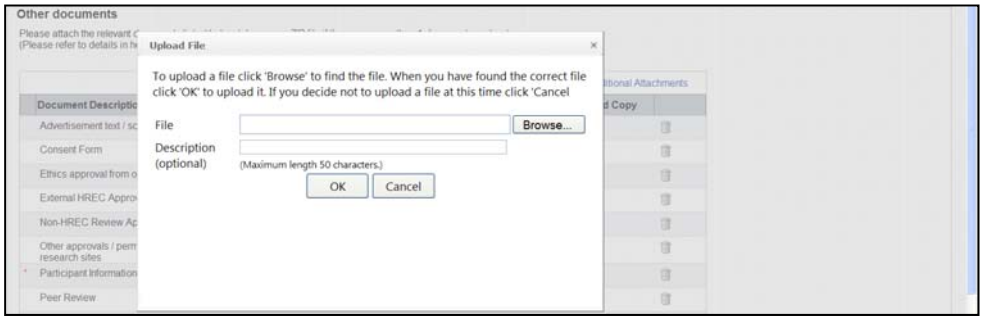
5

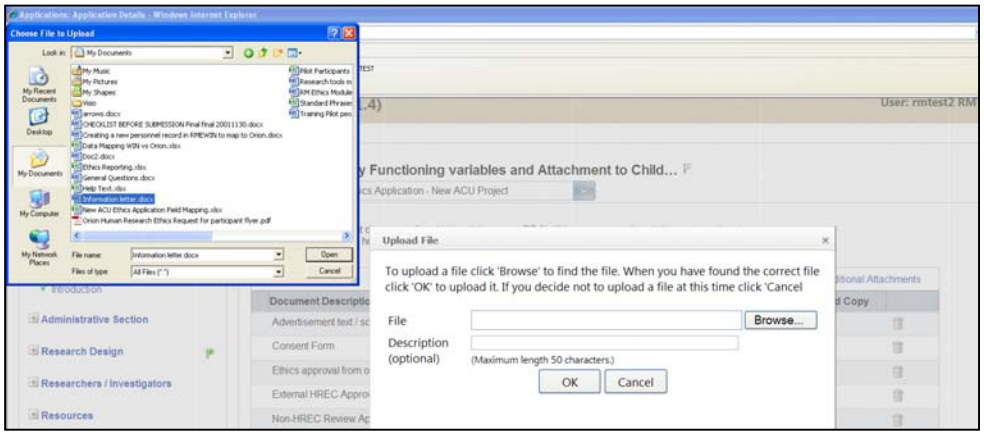

Document Description
Reference (Document Title)
Soft Copy
Hard Copy
Advertisement text / script
Research tools methods advert.docx
Consent Form
Ethics approval from overseas research sites
External HREC Approval letters
Non-HREC Review Approval letters
Other approvals / permissions from overseas research sites
Participant Information Letter
Proforma for gaining the consent of the person responsible*
Research Proposal
Your document's file name will appear in the Reference column

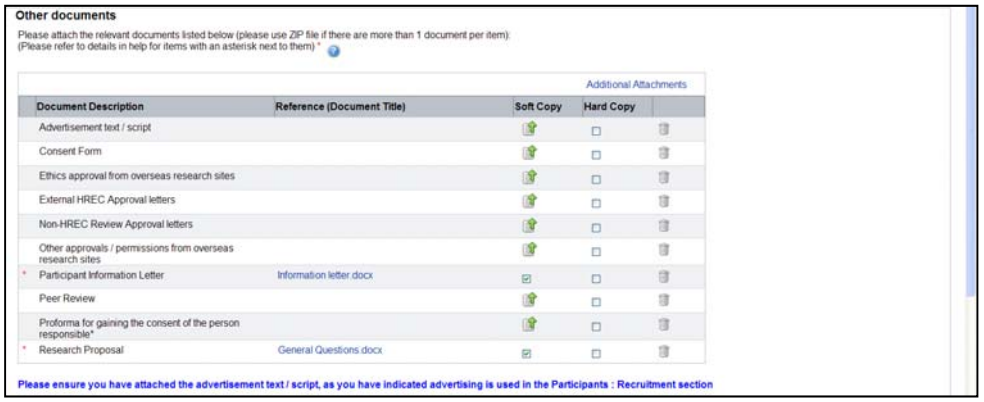
5.8 Changing attachments


Document Description
Reference (Document Title)
Soft Copy
Hard Copy
Advertisement text / script
Consent Form
Ethics approval from overseas research sites
External HREC Approval letters
Non-HREC Review Approval letters
Other approvals / permissions from overseas research sites
Participant Information Letter
Researchproposalexample.doc
Peer Review
Proforma for gaining the consent of the person responsible*
Research Proposal
General Questions.docx
Please ensure you have attached the advertisement text / script, as you have indicated advertising is used in the Participants : Recruitment section
To change the attachment, click on the tick box


Document Description
Reference (Document Title)
Soft Copy
Hard Copy
Advertisement text / script
Consent Form
Ethics approval from overseas research sites
External HREC Approval letters
Non-HREC Review Approval letters
Other approvals / permissions from overseas research sites
Participant Information Letter
Researchproposalexample.doc
Peer Review
Proforma for gaining the consent of the person responsible*
Research Proposal
General Questions.docx
The tick box icon will change back to the upload document icon, click to browse and upload new attachment

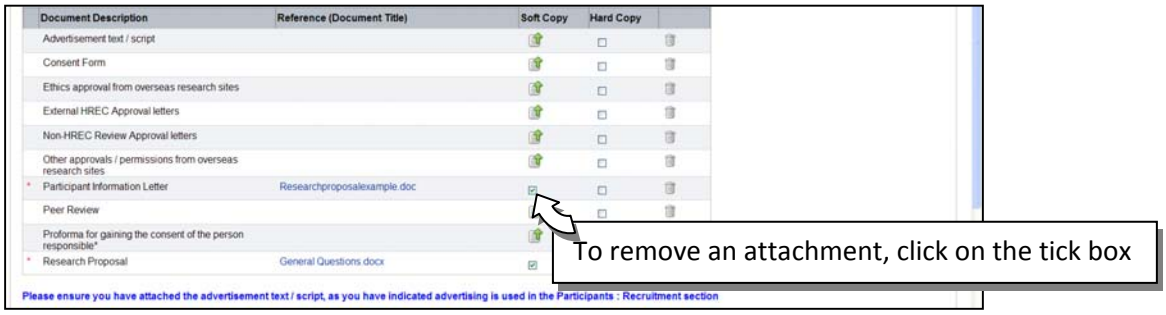

Other documents
Upload File
To upload a file click 'Browse' to find the file. When you have found the correct file click 'OK' to upload it. If you decide not to upload a file at this time click 'Cancel
File
Browse...
Description (optional)
(Maximum length 50 characters.)
OK
Cancel

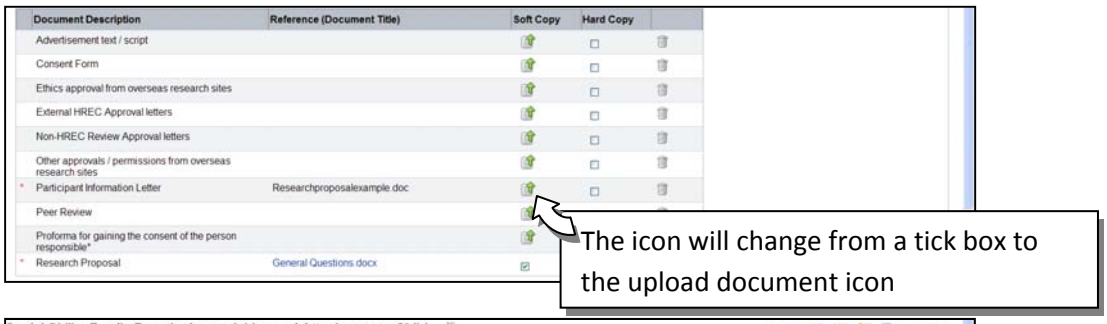

Choose File to Upload
Upload File
To upload a file click 'Browse' to find the file. When you have found the correct file click 'OK' to upload it. If you decide not to upload a file at this time click 'Cancel
File
Browse...
Description (optional)
(Maximum length 50 characters.)
OK
Cancel
Administrative Section
Research Design
Researchers / Investigators
Resources

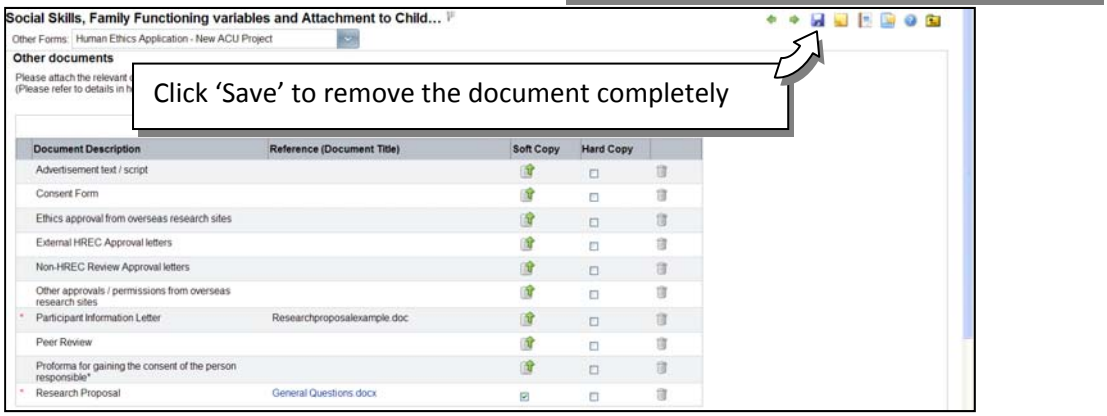

Other documents
Please attach the relevant documents listed below (please use ZIP file if there are more than 1 document per item).
(Please refer to details in help for items with an asterisk next to them) *
Additional Attachments
Document Description
Reference (Document Title)
Soft Copy
Hard Copy
Advertisement text / script
Consent Form
Ethics approval from overseas research sites
External HREC Approval letters
Non-HREC Review Approval letters
Other approvals / permissions from overseas research sites
Participant Information Letter
Information letter.docx
Peer Review
Proforma for gaining the consent of the person responsible*
Research Proposal
General Questions.docx
Please ensure you have attached the advertisement text / script, as you have indicated advertising is used in the Participants : Recruitment section

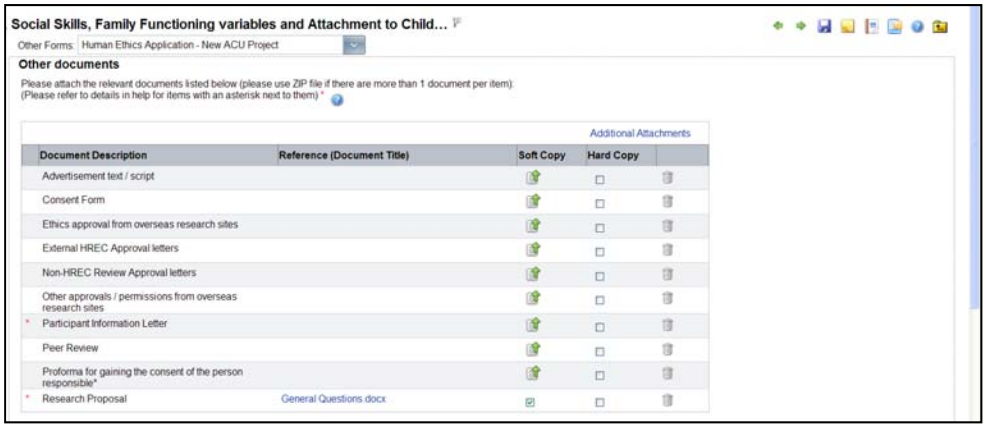
⚠ Please ensure you use unique file names each time you upload your document(s) as the system will only allow a document with a specified file name to be uploaded once (i.e. if amendments are required, the newly uploaded file name will need to be different from the original). Please use version numbers or dates to ensure the system will allow you to upload amended attachments.

5.9 Removing an Attachment


Document Description
Reference (Document Title)
Soft Copy
Hard Copy
Advertisement text / script
Consent Form
Ethics approval from overseas research sites
External HREC Approval letters
Non-HREC Review Approval letters
Other approvals / permissions from overseas research sites
Participant Information Letter
Researchproposalexample.doc
Peer Review
Proforma for gaining the consent of the person responsible*
Research Proposal
General Questions.docx
Please ensure you have attached the advertisement text / script, as you have indicated advertising is used in the Participants : Recruitment section
To remove an attachment, click on the tick box

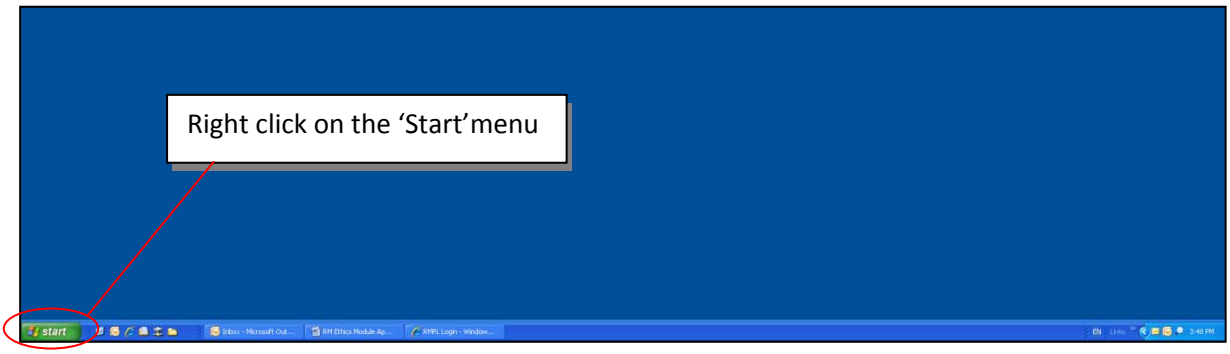

Document Description
Reference (Document Title)
Soft Copy
Hard Copy
Advertisement text / script
Consent Form
Ethics approval from overseas research sites
External HREC Approval letters
Non-HREC Review Approval letters
Other approvals / permissions from overseas research sites
Participant Information Letter
Researchproposalexample.doc
Peer Review
Proforma for gaining the consent of the person responsible*
Research Proposal
General Questions.docx
The icon will change from a tick box to the upload document icon

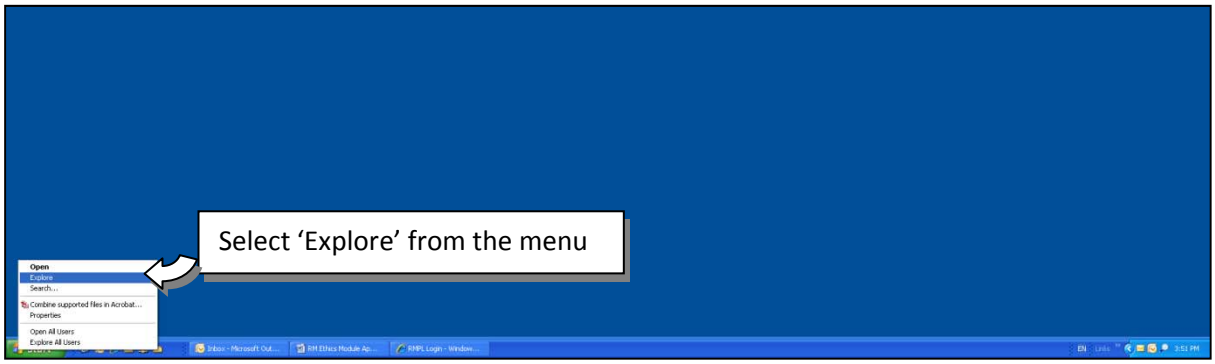

Social Skills, Family Functioning variables and Attachment to Child...
Other Forms: Human Ethics Application - New ACU Project
Other documents
Click 'Save' to remove the document completely
Document Description
Reference (Document Title)
Soft Copy
Hard Copy
Advertisement text / script
Consent Form
Ethics approval from overseas research sites
External HREC Approval letters
Non-HREC Review Approval letters
Other approvals / permissions from overseas research sites
Participant Information Letter
Researchproposalexample.doc
Peer Review
Proforma for gaining the consent of the person responsible*
Research Proposal
General Questions.docx

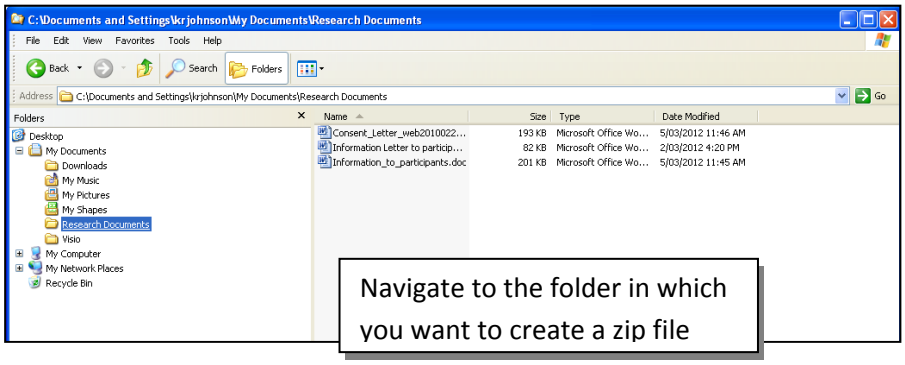

Social Skills, Family Functioning variables and Attachment to Child...
Other Forms: Human Ethics Application - New ACU Project
Other documents
Please attach the relevant documents listed below (please use ZIP file if there are more than 1 document per item):
(Please refer to details in help for items with an asterisk next to them) *
Additional Attachments
Document Description
Reference (Document Title)
Soft Copy
Hard Copy
Advertisement text / script
Consent Form
Ethics approval from overseas research sites
External HREC Approval letters
Non-HREC Review Approval letters
Other approvals / permissions from overseas research sites
Participant Information Letter
Peer Review
Proforma for gaining the consent of the person responsible*
Research Proposal
General Questions.docx

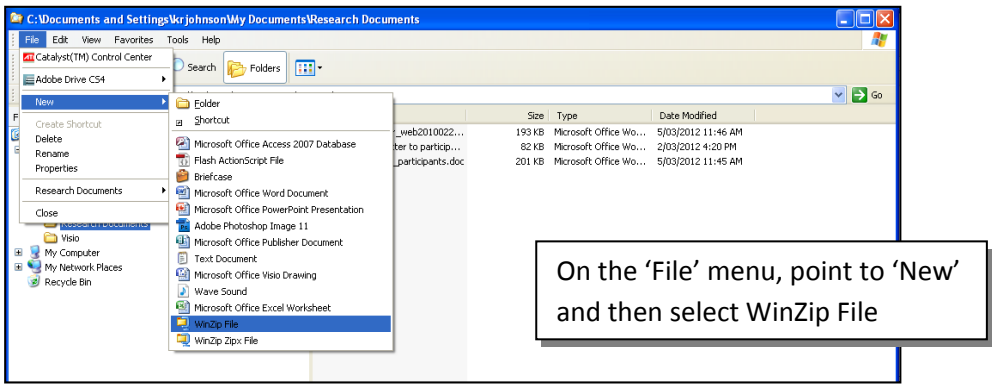
5.10 Creating a zip file

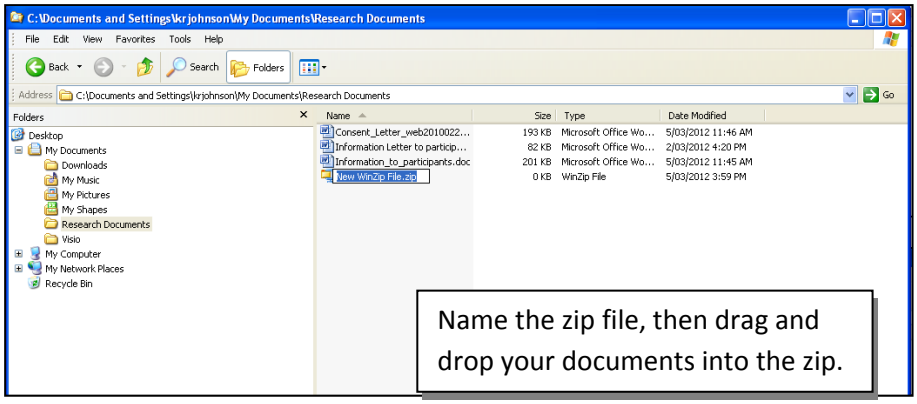
In cases where there are multiple documents for a particular document type, a zip file will need to be created.





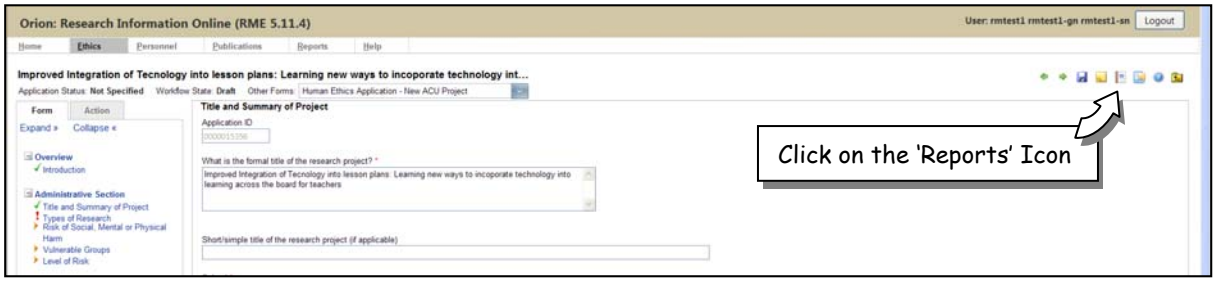

C:\Documents and Settings\krjohnson\My Documents\Research Documents
Navigate to the folder in which you want to create a zip file

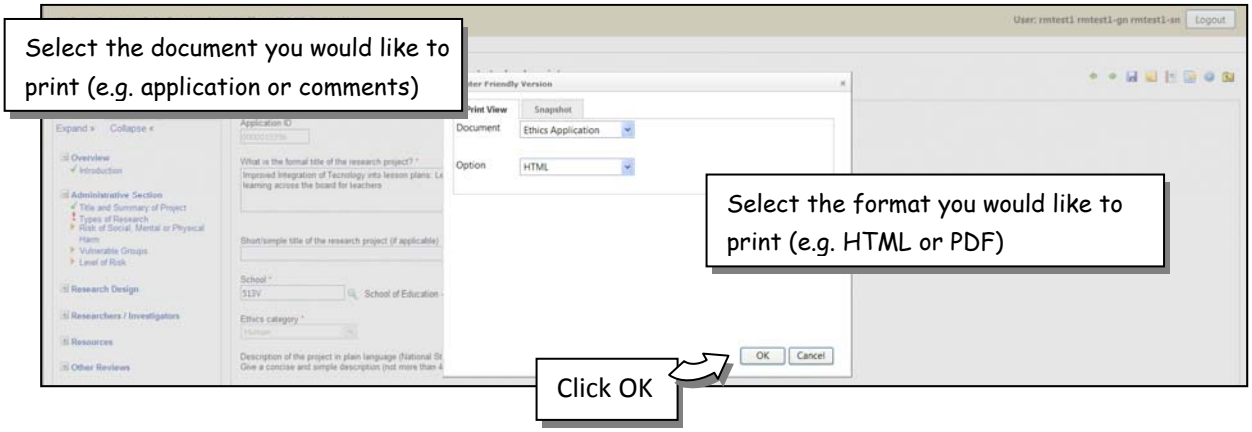

C:\Documents and Settings\krjohnson\My Documents\Research Documents
On the 'File' menu, point to 'New' and then select WinZip File

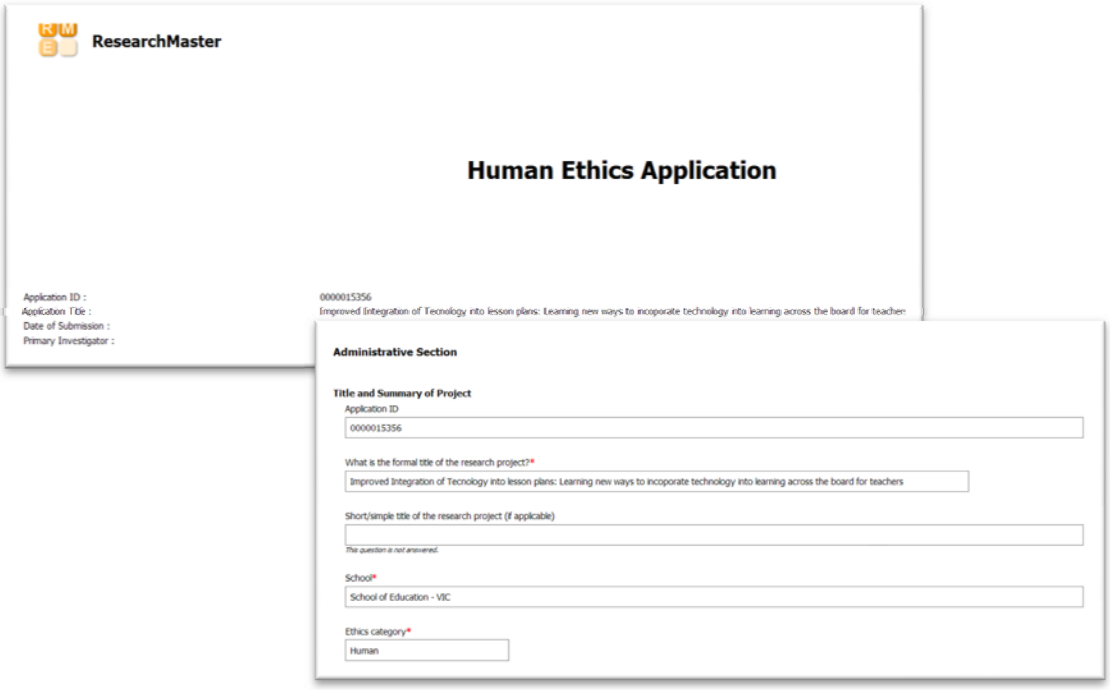

C:\Documents and Settings\krjohnson\My Documents\Research Documents
Name the zip file, then drag and drop your documents into the zip.

5.11 Printing Applications and associated information

Applicants can print their application and any associated comments, if desired. It can be printed as a PDF or HTML. When using the print function to print an application (submitted or not), all questions and responses will appear in the printout. If a question has not been completed, this will also be indicated.



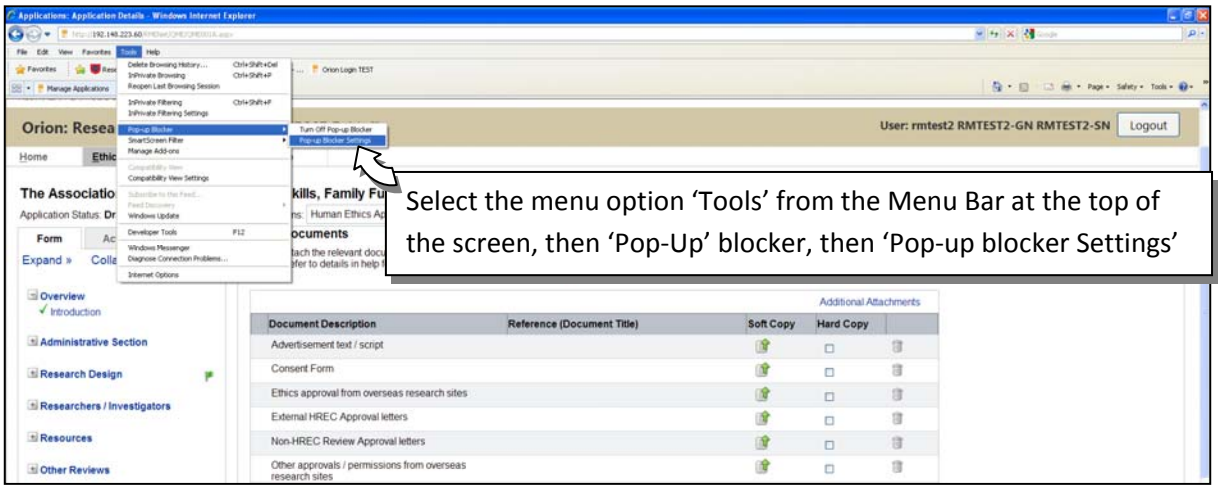

Select the document you would like to print (e.g. application or comments)
Select the format you would like to print (e.g. HTML or PDF)
Click OK

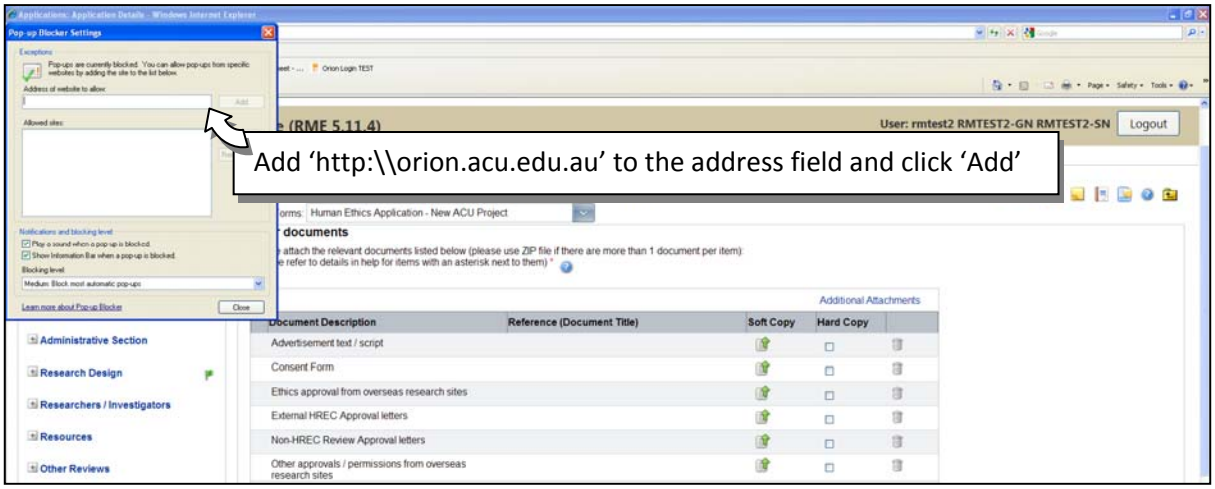

ResearchMaster
Human Ethics Application
Application ID :
Application Title :
Date of Submission :
Primary Investigator :
0000015356
Improved Integration of Tecnology into lesson plans: Learning new ways to incoporate technology into learning across the board for teacher
Administrative Section
Title and Summary of Project
Application ID
0000015356
What is the formal title of the research project?*
Improved Integration of Tecnology into lesson plans: Learning new ways to incoporate technology into learning across the board for teachers
Short/simple title of the research project (if applicable)
This question is not answered.
School*
School of Education - VIC
Ethics category*
Human

⚠ MAC/iPad users will not be able to print the application, comments or documents reports

⚠ Pop-up blockers will need to be disabled for http:\\orion.acu.edu.au in order for the report to be generated as they appear in a new window

To disable pop-up blockers (windows):

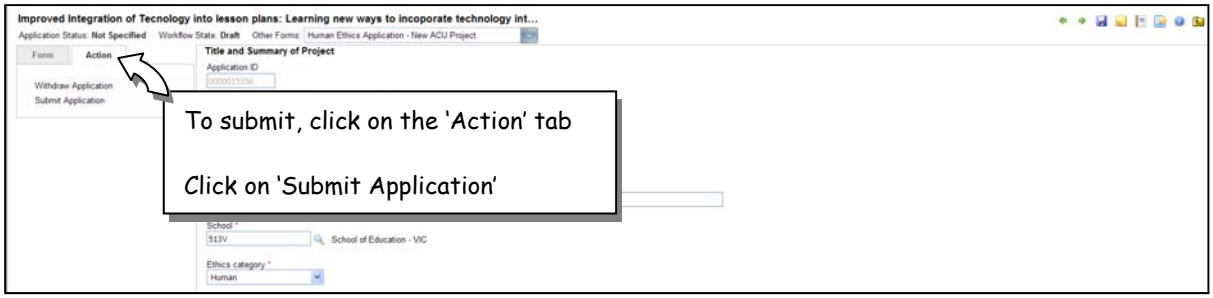



Add 'http:\\orion.acu.edu.au' to the address field and click 'Add'
Pop-up Blocker Settings
User: rmtest2 RMTEST2-GN RMTEST2-SN
Logout
Human Ethics Application - New ACU Project
documents
Additional Attachments
Document Description
Reference (Document Title)
Soft Copy
Hard Copy
Advertisement text / script
Consent Form
Ethics approval from overseas research sites
External HREC Approval letters
Non-HREC Review Approval letters
Other approvals / permissions from overseas research sites
Administrative Section
Research Design
Researchers / Investigators
Resources
Other Reviews

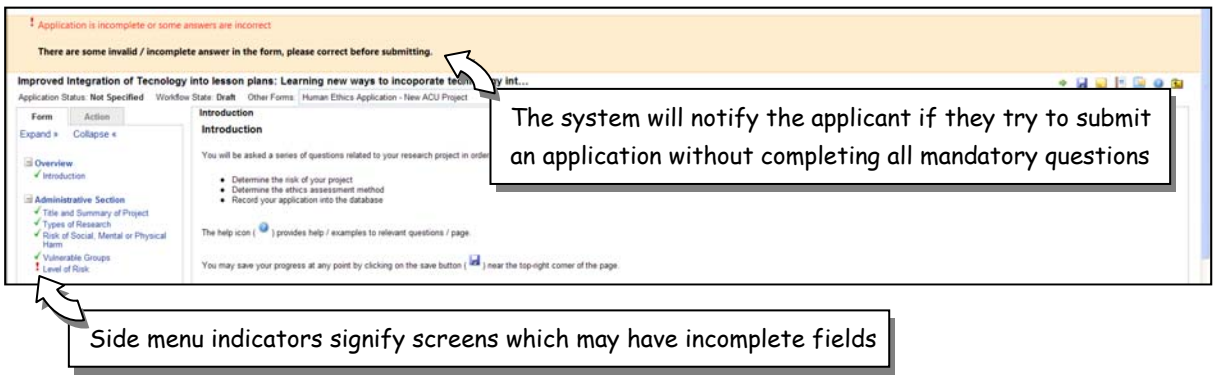
6. Submitting a New Application

6.1 Submitting an application

Only once all mandatory fields have been completed can an applicant submit their Human Research Ethics Application for review by the Ethics Office.



The system will notify the applicant if they try to submit an incomplete application through an error message- the incomplete page and section will also be flagged with '!'


The system will notify the applicant if they try to submit an application without completing all mandatory questions
Side menu indicators signify screens which may have incomplete fields

Once the application has been submitted and/or a change has been made to the application by the Ethics Officer, the applicant will be notified by email. The email will acknowledge receipt of the application, which also details the next steps for the application. Generally, subsequent steps after submission are one of the following:

- Ethics Officer requests more information regarding the application
- Application referred to Panel Members for review (Low Risk applications)
- Application referred to the HREC (more than low risk Applications)

The applicant may also check the status of the application using the applications menus.

- Once the application has gone to a reviewer, the applicant will not be able to access the application until the review process has been completed. If the applicant requires a change to be made during the review stage, please contact the Ethics Officer who will revert the application back to the researcher.

6.2 Student Applications

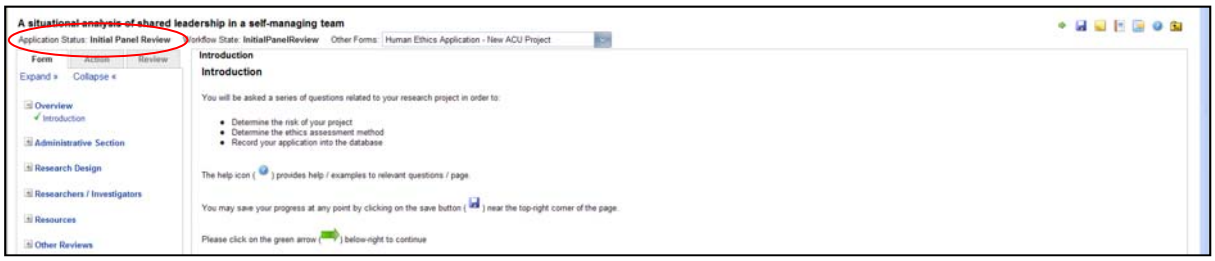
Supervisors are expected to work on the Ethics Application with their students whilst it is still in draft form. Whilst the application is in draft form, the student and supervisor may access the application and communicate using the comments functionality, or alternatively, via more traditional means (i.e. email, phone calls etc.)

The supervisor has a choice of whether the student creates the application, or if the supervisor creates the application. If the supervisor creates the application, they will then need to give access to the student by naming the student on the Researcher Details page. The person who creates the application must to the one to submit.

- If the supervisor is the creator of the application, a checklist will appear at the end of the form, which asks the supervisor to take responsibility for the project and confirm they are aware of the application. Once the supervisor submits the application, the Ethics Officer will be aware that the application is complete and ready for review by the panel or comittee.

- If the student is the creator of the form, the checklist will not appear until the application has been redirected to the supervisor for sign off and confirmation that the application is complete and ready to be submitted for review. This process is described below at 7.2.1 Supervisor – approving student application

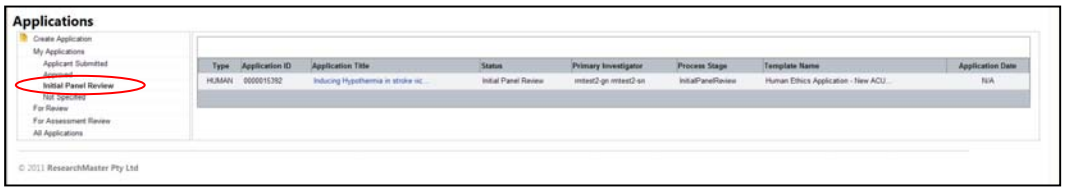
Once the supervisor has been allocated by the Ethics Officer for review, the status will change to Initial Review Panel and the Supervisor will receive an email prompting them to log in and review the application.


A situational analysis of shared leadership in a self-managing team
Application Status: Initial Panel Review
Workflow State: InitialPanelReview
Other Forms:
Human Ethics Application - New ACU Project
Form
Action
Review
Expand »
Collapse «
Overview
Introduction
Administrative Section
Research Design
Researchers / Investigators
Resources
Other Reviews
Introduction
Introduction
You will be asked a series of questions related to your research project in order to:
Determine the risk of your project
Determine the ethics assessment method
Record your application into the database
The help icon ( ) provides help / examples to relevant questions / page.
You may save your progress at any point by clicking on the save button ( ) near the top-right corner of the page.
Please click on the green arrow ( ) below-right to continue

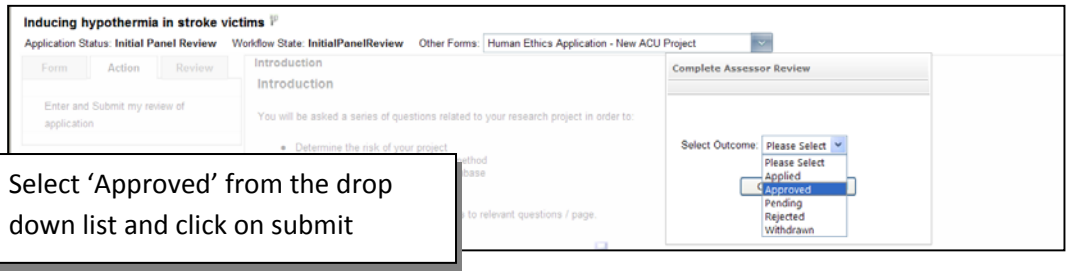
***7.2.1 Supervisor**- approving student application*

If the student is the creator of the application, and has has submitted their application, the application will be re-directed to the supervisor by the Ethics Officer for sign off before submission to HREC or the Panel.

Applications requiring approval prior to submission to the Ethics Officer will appear under the menu 'Initial Review Panel' in the Applications Menu.



Inducing hypothermia in stroke victims
Application Status: Initial Panel Review
Form
Action
Enter and Submit my review of application
Click on the 'Action' tab, then click 'Enter and Submit my review of the application'
Determine the risk of your project
Determine the ethics assessment method
Record your application into the database
The help icon ( ) provides help / examples to relevant questions / page.



If the supervisor is unaware of the submitted student application, 'Pending' would be selected from the drop down list on the Assessor Review screen above.

⚠ Once the application has gone to a reviewer, the applicant will not be able to access the application until the review process has been completed. If the applicant requires a change to be made during the review stage, please contact the Ethics Officer who will revert the application back to the researcher.

7. Amendments

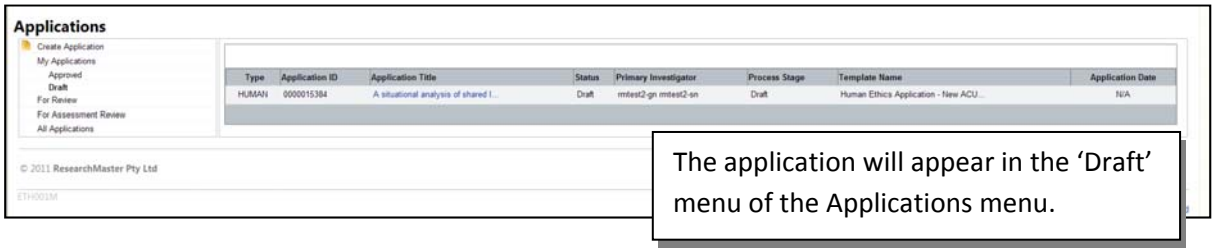
Amendments may be required at different stages of the review process:

- Prior to HREC/ERP Review
- After ERP Review (Negligible or low risk applications)
- After HREC Meeting (More than low risk applications)

7.1 Amendments prior to HREC/ERP Review

If the Ethics Officer assesses the application and feels that more information or explanation is required prior to submission to HREC/ERP, they may send the application back to the applicant for amendments. Amendments are communicated via the Comments function.

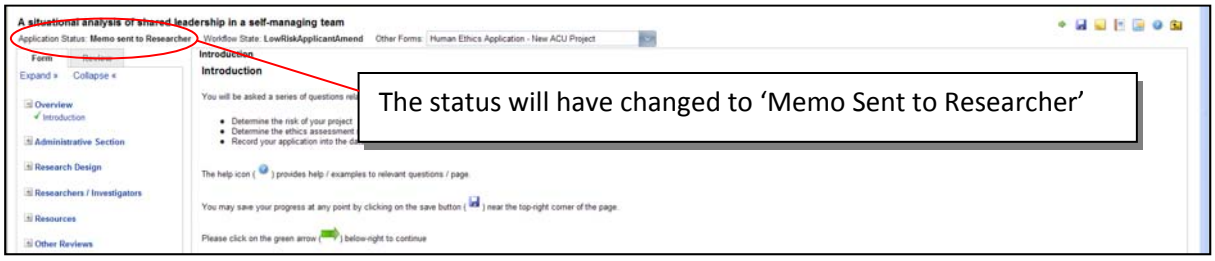
An email notification will automatically be sent to the applicant requesting they log in to Orion and make requested amendments specified in the Comments.



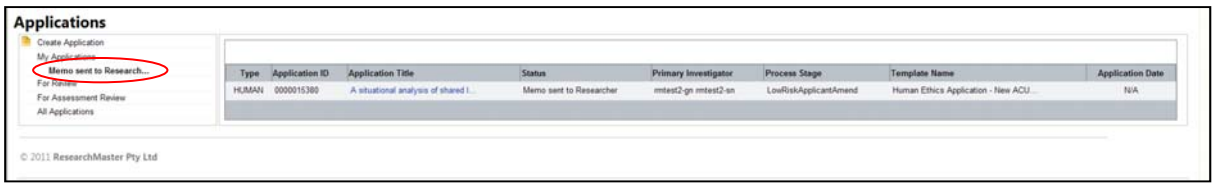
After the requested amendments have been made, the applicant can re-submit using the same process as they did during the initial submission.

7.2 Amendments after ERP/HREC Review

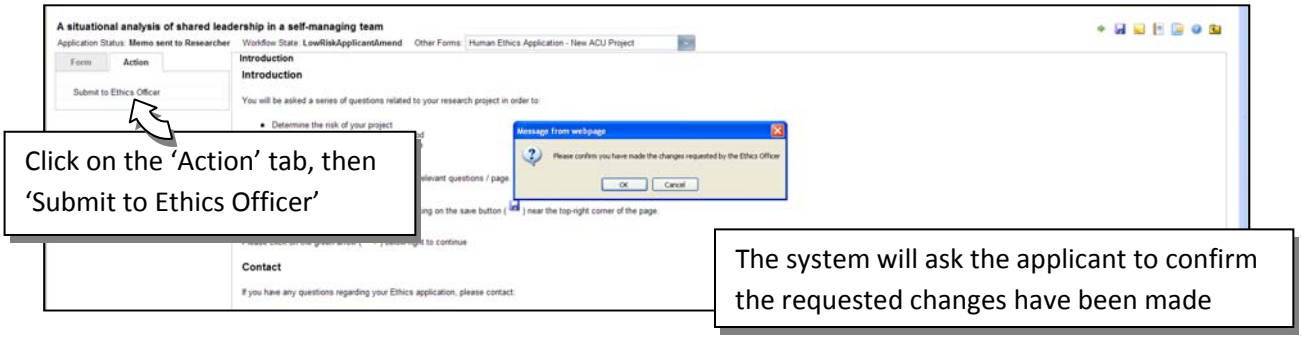
If amendments are required after ERP review, an email will automatically be sent to the researcher requesting they check the application comments and make required amendments.



The applicant will find their application requiring amendments at this stage of the process in the 'Memo Sent to Researcher' menu option in the Applications menu.



After the comments have been responded to (please see section on comments), the applicant would then submit their application to the Ethics Officer via the 'Action' tab within the application.


A situational analysis of shared leadership in a self-managing team
Application Status: Memo sent to Researcher
Workflow State: LowRiskApplicantAmend
Other Forms: Human Ethics Application - New ACU Project
Form
Action
Submit to Ethics Officer
Introduction
Introduction
You will be asked a series of questions related to your research project in order to:
Determine the risk of your project
Message from webpage
Please confirm you have made the changes requested by the Ethics Officer
OK
Cancel
Contact
If you have any questions regarding your Ethics application, please contact:

Click on the 'Action' tab, then 'Submit to Ethics Officer'

The system will ask the applicant to confirm the requested changes have been made

8. Viewing and Making Comments

In some cases, Supervisors, Ethics Officer or the Human Research Ethics Committee may require applicants to make an amendment to their project or clarify certain points. In these situations, an email will be sent to the Researcher/Investigator, prompting them to login in to Orion in order to review the comments and respond to questions or requests for more information. These comments can be related to the application as a whole (application comments) or relating to a specific section or question (page comments).

Researchers may also wish to make comments regarding their application to communicate with the Ethics Officers and/or HREC.

There are two types of comments applicants will see for both Application Comments and Page Comments:

- General Comments are used to make notes or observations about the application. No action is required. These are indicated by a white flag.
- Action Comments are used to request modifications or in response to a question. This is how applicants can respond to any questions raised by reviewers. These are indicated by a red flag initially and progress to a green flag once the comment has been resolved

8.1 Comment Flags

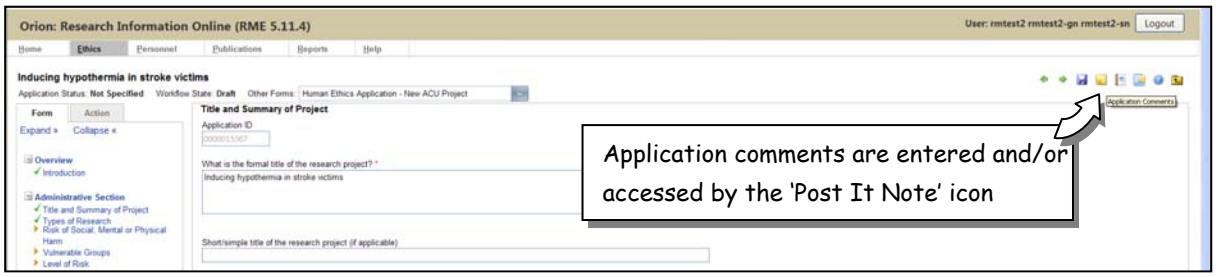
Flag	Description	Priority
Red	A reviewer has entered an action comment on a page	1 – Highest
Amber	The applicant has responded to the action comment	2
Green	The reviewer has resolved the action comment that the applicant has responded to	3
White	There is a general note on the page- no action is required	4- Lowest

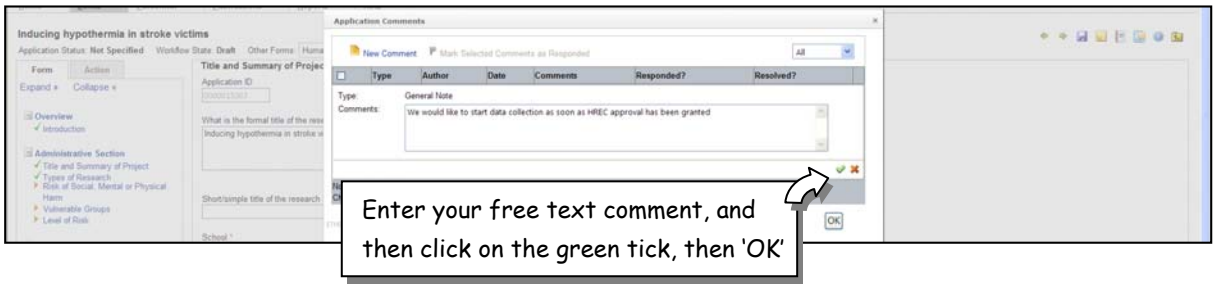
Coloured flags are used to indicate that there are page level comments in areas of the application tree. There is a flag against each page that has comments and a flag against the section if there is a flagged page within it. The colour of the flag indicates the priority of the comment.

If there are multiple comments of various priorities on a page or section, the highest priority flag will be shown. The image displays the coloured flags.

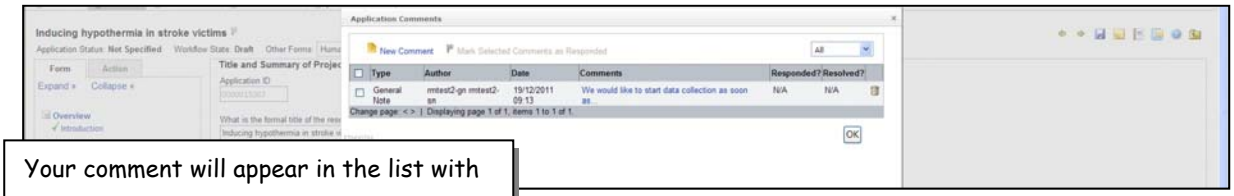
8.2 Application Comments

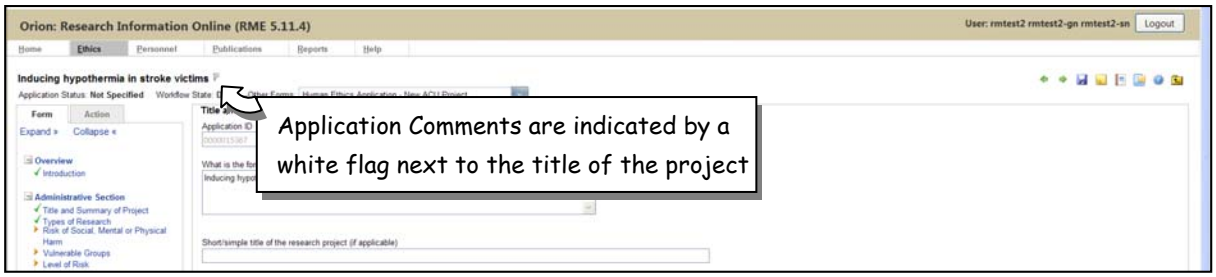
Application comments refer to general comments relating to the application as a whole. These may be used by the applicant themselves, or by the reviewers.





An unsaved comment will not be saved when you close the comments dialogue box. Make sure you save your comment first

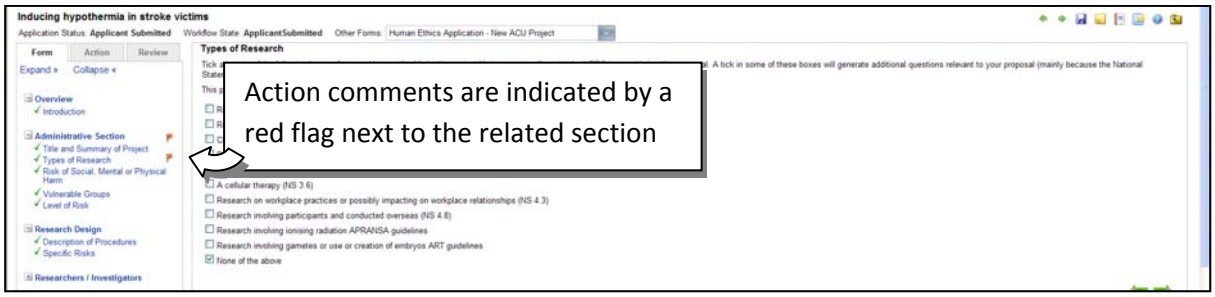


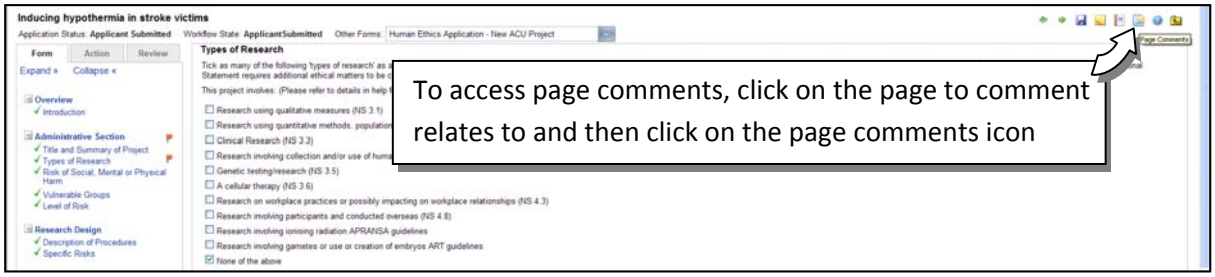

Orion: Research Information Online (RME 5.11.4)
Application Comments are indicated by a white flag next to the title of the project

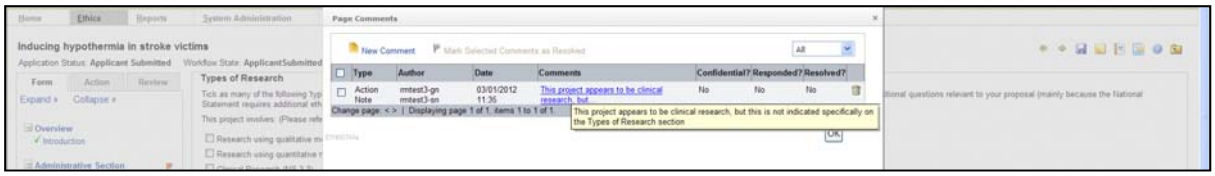
8.3 Page Comments

Page comments refer to comments relating to a specific page or question. Page comments are indicated by a coloured flag which is located beside the page it relates to. Comments that require action by the researcher are indicated by a red flag.

To access the Page Comment, click on the page the comment relates to and then click on the page comment icon.





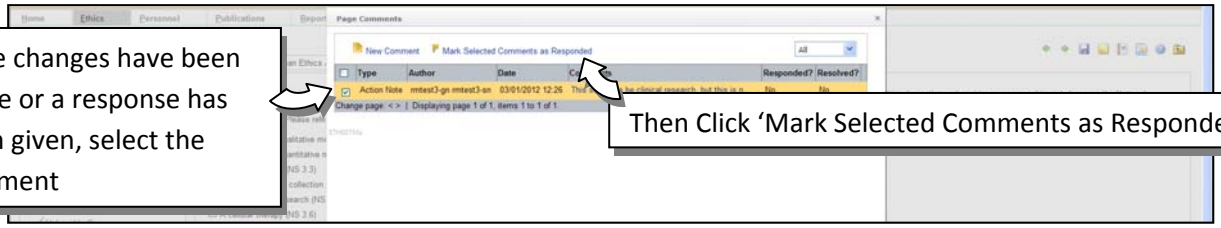


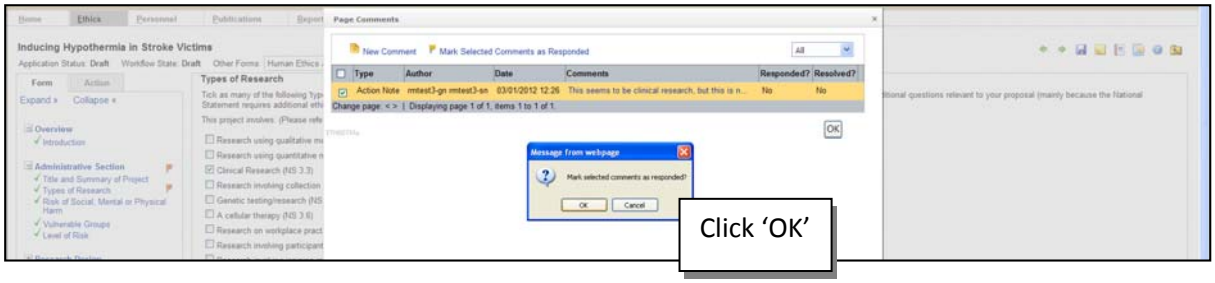
If changes are required or specific questions have been made by reviewers, the applicant can amend the actual application (i.e. attaching additional documents, or expanding explanation for a specific question) or they can respond using the comments feature.

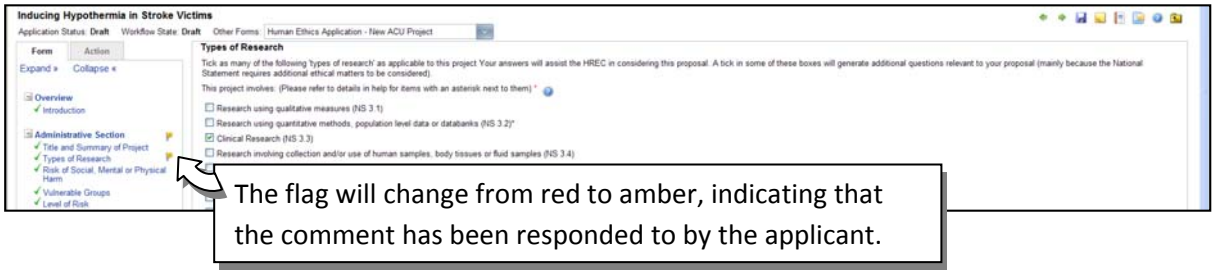
In cases where the action comment is requesting for a box to be ticked or a date changed, please make the change to the question the comment relates to (e.g. changes to project start and end dates). Where an action note relates to a text box, please leave the text in the actual application form in its original state. These comments can be responded to by creating a new comment and entering the response (e.g. expanding on the research methodology)

Once comments are answered by the researcher, the reviewer comments can be marked as 'Responded' by selecting the comment and then clicking 'Mark Selected Comments as Responded'.

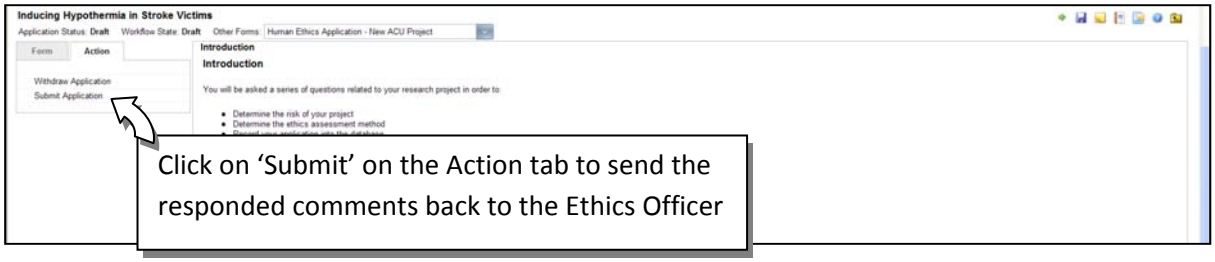
⚠ Please Note: Once comments have been marked as responded, the page it relates to will be locked and no longer be able to be edited.


Once changes have been made or a response has been given, select the comment
Then Click 'Mark Selected Comments as Responded'

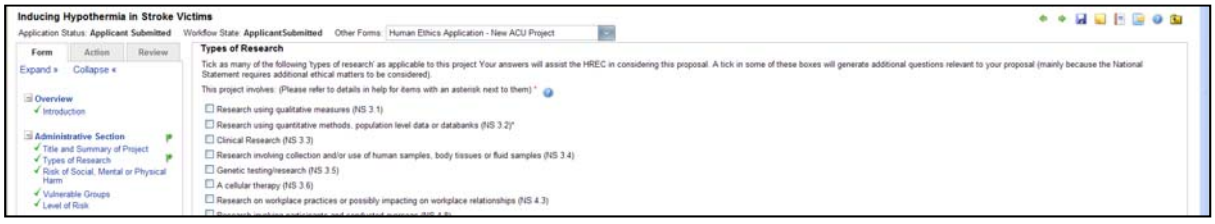




⚠ Please ensure that tracked changes are used when making changes to attachments



Once the comment has been reviewed and accepted by the Ethics Officer, they will mark the comment as 'Resolved' and the flag will change from amber to green indicating that the action item is complete.



8.4 Deleting Comments

It is possible to delete comments if required by clicking on the delete icon.

9. Approval and Rejections

After the application has been reviewed by HREC/ERP, the application may either be approved or rejected.

9.1 Rejected Applications

In the case where the application has been rejected, the Ethics Officer will create comments within the application explaining the reasons for the rejection. The status of the rejected applications will be 'Rejected' and an email is sent to the applicant updating them of the change in status. Once the applicant logs into the system, they will be able to view the comments outlining the reasons for rejection.

Rejected applications will be found in the 'Rejections' folder on the applications page.

9.2 Approved Applications

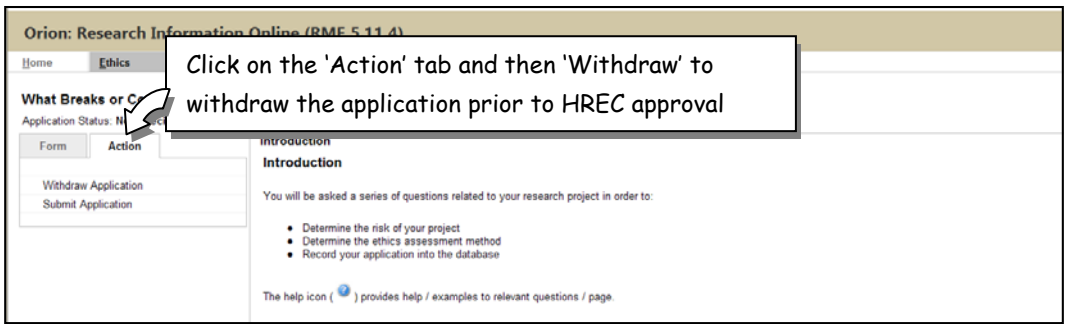
Once the application has been approved by the Ethics Officer, the status will change to approved and an email will be sent to the applicant informing them of the approved application. Once approved, the application will be location in the 'Approved' folder on the Applications List page.

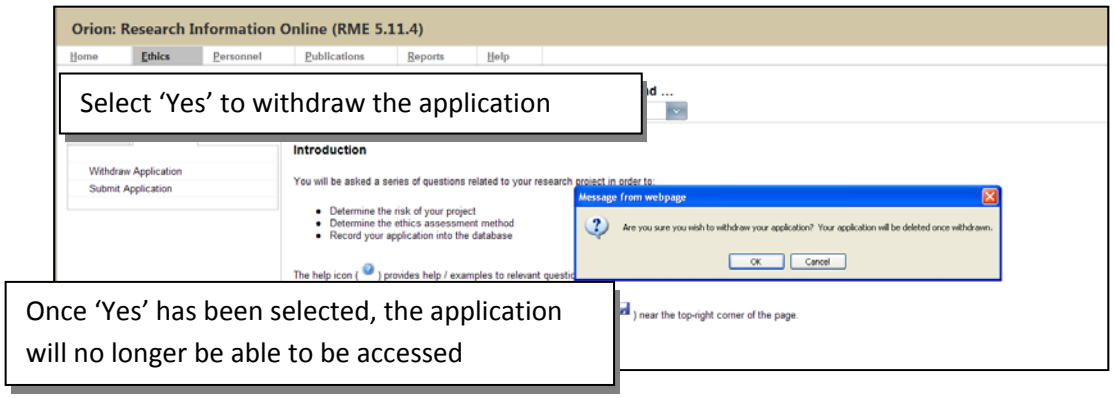
10. Withdrawing an application

If an applicant would like to withdraw their application prior to ERP or HREC approval, they can withdraw the created application. Once an application has been approved, the applicant will not be able to use this function to withdraw their application. To withdraw or abandon a project, the applicant will need to submit an update through the Annual Progress Report.

The applicant may withdraw their application only whilst it is in draft form. If an applicant would like to withdraw their application part way through the approval process, they will need to email the Ethics Officer, who will process their request.

10.1 Withdrawing an application prior to submission to Ethics Officer


Click on the 'Action' tab and then 'Withdraw' to withdraw the application prior to HREC approval
Home
Ethics
Form
Action
Withdraw Application
Submit Application
Introduction
You will be asked a series of questions related to your research project in order to:
Determine the risk of your project
Determine the ethics assessment method
Record your application into the database



10.2 Withdrawing an application during the approval process

In order to withdraw an application after it has been submitted, but before approval, please send your request to withdraw via email to the Ethics Officers res.ethics@acu.edu.au.

11. Glossary

HREC	Human Research Ethics Committee - Applications that are more than low risk may need to be reviewed by this committee
ERP	Expedited Review Panel - Applications that are low risk or negligible risk may not be required to go to the HREC and can be reviewed by Panel members
Negligible Risk	Negligible risk describes research in which there is no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than inconvenient. Examples of inconvenience may include filling in a form, participating in a street survey, or giving up time to participate in research (e.g. a 10 minute survey relating to non-sensitive information)
Low Risk	Low risk research is research in which the only foreseeable risk is one of discomfort. Discomfort can involve body and/or mind and include, for example, minor side effects of medication, the discomforts relating to measuring blood pressure, and anxiety induced by an interview (e.g. a time commitment of more than 30 minutes and can include sensitive and non-sensitive information. Low risk research can involve some physical activity or testing).
More than Low Risk	More than Low Risk research includes research with the potential for physical or psychological harms, devaluation of personal worth, social harms, including damage to social networks, economic harms and legal harms (e.g. all collection of information of a highly sensitive nature and any invasive or experimental procedures).
Individually Identifiable Data	From which the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth or address.
Re-identifiable Data	From which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets
Non-Identifiable Data	Which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person's identity remains unknown